federal register

Wednesday
July 25, 1979

Part II

Environmental Protection Agency

Endrin; Intent To Cancel Registrations and Denial of Applications for Registration of Pesticide Products Containing Endrin, and Statement of Reasons

ENVIRONMENTAL PROTECTION AGENCY

[FRL 1278-7; OPP-30000/4C]

Endrin; Intent To Cancel Registrations and Denial of Applications for Registration of Pesticide Products Containing Endrin, and Statement of Reasons

AGENCY: Office of Pesticide Programs, Environmental Protection Agency (EPA).

ACTION: Notice of Intent to Cancel Registrations and denial of Applications for Registration of Pesticide Products Containing Endrin; Analysis of Comments (Position Document 4) Concerning Endrin.

SUMMARY: On July 27, 1976, the Environmental Protection Agency published in the **Federal Register** (41 FR 31316) a notice of rebuttable presumption against registration and continued registration (RPAR) of pesticide products containing endrin. Registrants and other interested persons were provided the opportunity to submit data and information to rebut the presumption. After reviewing all available information, the Agency determined that three risk presumptions announced in the endrin RPAR had not been rebutted—the risks of significant population reductions of non-target organisms, acute toxicity to wildlife, and teratogenicity—and that the risks posed by the uses of endrin were of sufficient concern to require the Agency to consider whether there were offsetting economic, social, or environmental benefits.

The Agency also reviewed information relating to the benefits of the uses of endrin and, after considering risks in relation to benefits, determined that some risks may be reduced by modifying the terms and conditions of registration for some uses and by cancelling or denying applications for registration for other uses. These preliminary decisions were announced in the Notice of Determination Concluding the Endrin RPAR, published on November 2, 1978 (43 FR 51132) (the "Preliminary Notice") and are detailed further in this Notice.

This Notice initiates actions to cancel unconditionally the registrations of the following uses of endrin: use on cotton in all areas east of interstate Highway #35; use on small grains to control all pests other than they army cutworm, the pale western cutworm and grasshoppers; use on apple orchards in Eastern States to control meadow voles; use on sugarcane to control the sugarcane borer; and use on ornamentals. This notice also notifies applicants for new registrations of these uses of endrin, as well as applicants for registration of endrin for use in unenclosed bird perch treatments, that these applications are denied.

This Notice also initiates actions to cancel the registrations of the following uses of endrin unless registrants modify the terms and conditions of registration as required by this Notice: use on cotton west of Interstate Highway #35; use on small grains to control army cutworms and pale western cutworms; use on apple orchards in Eastern States to control the pine vole and in Western States to control meadow voles; use on sugarcane to control the sugarcane bettle; use for conifer seed treatment; and use in enclosed bird perch treatments. This Notice also notifies applicants for new registrations of these uses of endrin, as well as applicants for registration of endrin for use as tree paint (in Texas), for use on alfalfa and clover seed crops (in Colorado), and for use on small grains to control grasshoppers (in Montana), that these applications are denied unless they are corrected to include the terms and conditions of registration specified in this Notice.

FOR FURTHER INFORMATION CONTACT: William S. Cox, Project Manager, Special Pesticide Review Division, Office of Pesticide Programs (TS-791), EPA, 401 M Street, SW., Washington, DC 20460, 202-557-7973.

SUPPLEMENTARY INFORMATION: Position Document 4 (PD 4), which accompanies this Notice, discusses in detail the comments which were received concerning Position Document ⅔ (P ⅔) and the Preliminary Notice. The comments of the FIFRA Scientific Advisory Panel and the Secretary of Agriculture are included in their entirety as Appendices to PD 4.

I. Introduction

On October 20, 1978, the Environmental Protection Agency issued a Notice of Determination pursuant to 40 CFR 162.11(a)(5), Concluding the Endrin RPAR (the "Preliminary Notice"). (43 FR 51132, November 2, 1978). The Preliminary Notice was accompanied by a Position Document ("PD") ⅔, which set forth in detail the Agency's analysis of comments received during the rebuttal phase of the endrin RPAR, and the Agency's reasons and factual bases for the regulatory actions which it initiated.

With respect to the principal uses of endrin, the Agency determined: (1)(a) That the risks of the uses of endrin on cotton in all States east of the Mississippi River and in Arkansas, Louisiana, Missouri and those portions of Oklahoma and Texas east of Interstate Highway #35 are greater than the social, economic and environmental benefits of use; (b) that the risks of the use of endrin on cotton on other areas are greater than the social, economic and environmental benefits unless risk reductions are accomplished by modifications in the terms of conditions of registration, as described in the Preliminary Notice; (2)(a) that the risks of the uses of endrin on small grains to control pests other than army cutworms, pale western cutworms and grasshoppers are greater than the social, economic and environmental benefits of use; (b) that the risks of the uses of endrin on small grains to control army cutworms, pale western cutworms, and grasshoppers are greater than the social, economic and environmental benefits unless risk reductions are accomplished by modifications in the terms or conditions of registration, as described in the preliminary Notice; and (3)(a) that the risks of the use of endrin on apple orchards in Eastern States to control meadow voles are greater than the social, economic and environmental benefits of use; (b) that the risks of the use of endrin on apple orchards in Eastern States to control the pine vole and in Western States to control meadow voles are greater than the social, economic and environmental benefits of use unless risk reductions are accomplished by modifications in the terms or conditions of registration, as described in the Preliminary Notice.

Accordingly, the Agency initiated actions to cancel or deny registrations for the use of endrin on cotton in all areas east of Interstate Highway #35, to cancel or deny registrations for the use of endrin on small grains to control pests other than the army cutworm, the pale western cutworm, and grasshoppers, and to cancel or deny registrations for the use of endrin on apple orchards in Eastern States to control meadow voles. Further, the Agency initiated action to cancel or deny registrations for the uses of endrin on cotton in areas other than those delineated for cancellation, on small grains to control the army cutworm, pale western cutworm and grasshoppers, and on apple orchards to control the pine vole in Eastern States and to control meadow voles in Western States unless the specified changes in the terms and conditions of registration are accomplished. The Agency further determined that these modifications in

the terms or conditions of registration accomplish significant risk reductions and that these risk reductions can be achieved without significant impacts on the benefits of the uses.

The Agency's conclusions and actions initiated with respect to those uses of endrin which account for a small proportion of the total endrin used were summarized in Section III of the Preliminary Notice.

The remainder of this Notice and the accompanying PD 4 set forth in detail the Agency's analysis of comments submitted by the Secretary of Agriculture, the FIFRA Scientific Advisory Panel (SAP) and other interested parties regarding the reasons and factual bases for the regulatory actions annouced in the Preliminary Notice.

This Notice is organized into four Sections. This introduction is Section I. Section II, entitled "Legal Background", is a general discussion of the regulatory framework within which these actions are taken. Section III and the accompanying PD 4 announce the regulatory actions which the Agency is implementing concerning endrin and set forth the bases for the decisions. Section IV, entitled "Procedural Matters", is a brief discussion of the procedures which will be followed in implementing the reguatory actions which the Agency is announcing in this Notice.

II. Legal Background

In order to obtain a registration for a pesticide under the Federal Insecticide, Fungicide and Rodenticide Act, as amended (FIFRA), a manufacturer must demonstrate that the pesticide satisfies the statutory standards for registration. That standard requires (among other things) that the pesticide perform its intended function without causing "unreasonable adverse effects on the environment" [section 3(c)(5)]. "Unreasonable adverse effects on the environment" is defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide" [section 2(bb)]. In effect, this standard requires a finding that the benefits of each use of the pesticide exceed the risks of use, when the pesticide is used in accordance with the terms and conditions of registration, or in accordance with widespread and commonly recognized practice. The manufacturer's burden of proving that a pesticide satisfies the registration standard continues as long as the registration remains in effect. Under § 6 of FIFRA, the Administrator is required to cancel the registration of a pesticide or modify the terms and conditions of registration whenever he determines that the pesticide no longer satisfies the statutory standard for registration.[1]

The Agency created the RPAR process to facilitate the identification of pesticide uses which may not satisfy the statutory standard for registration and to provide a structure for gathering and evaluating information about the risks and benefits of these uses. This structure invites public participation at major points in the evaluation process.

The RPAR process is set forth at 40 CFR 162.11. This section provides that a rebuttable presumption shall arise if a pesticide meets or exceeds any of the risk criteria set out in the regulations. After an RPAR is issued, registrants and other interested persons are invited to review the data upon which the presumption is based and to submit data and information to rebut the presumption. Respondents may rebut the presumption of risk by showing that the Agency's initial determination of risk was in error, or by showing that use of the pesticide is not likely to result in any significant exposure either to man or to the animal or plant populations of concern with regard to the adverse effect in question.[2] Further, in addition to submitting evidence to rebut the risk presumption, registrants may submit evidence as to whether the economic, social, and environmental benefits of the use of the pesticide subject to the presumption outweigh the risks of use.

The regulations require the Agency to conclude an RPAR by issuing a Notice of Determination. In that Notice, the Agency states and explains its position on the question whether the risk presumption has been rebutted. If the Agency determines that the presumption has not been rebutted, it also considers information relating to the social, economic, and environmental costs and benefits which registrants and other interested persons submitted to the Agency and any other benefits information known to the Agency. If the Agency determines that the risks of a pesticide use appear to outweigh its benefits, the RPAR process finally concludes with a Notice of Intent to Cancel or Denial of Application for Registration, pursuant to FIFRA section 6(b)(1) or section 3(c)(6).

When the uses of a pesticide appear to pose risks which are greater than benefits, the Agency considers modifications to the terms and conditions of registration which can reduce risk, and the impacts of such modifications to the terms or conditions of registration on the benefits of the use. The risk reduction measures, short of cancellation, which are available to the Agency include requiring changes in the directions for use on the pesticide's labeling, and classifying the pesticide for "restricted use", pursuant to FIFRA section 3(d).[3]

FIFRA requires the Agency to submit notices issued pursuant to section 6 to the Secretary of Agriculture for comment and to provide the Secretary of Agriculture with an analysis of the impact of the proposed action on the agricultural economy [section 6(b)]. The Agency is required to submit these documents to the Secretary at least 60 days before making the Notice effective by sending it to registrants or making it

[1] The statutory standard for registration also requires that the pesticide satisfy the labeling requirements of FIFRA. These requirements are set out in the statutory definition of "misbranded" [section 2(q)]. Among other things, that section provides that a pesticide is misbranded if "the labeling * * * does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any * * * [restrictions] imposed under secion 3(d) * * * are adequate to protect health and the environment." The Agency can require changes to the directions for use of a pesticide in most circumstances either by finding that the pesticide is misbranded if the labeling is not changed, or by finding that the pesticide would cause unreasonable adverse effects on the environment, unless labeling changes are made which accomplish risk reductions.

[2] 40 CFR 162.11(a)(4) provides that registrants and applicants may rebut a presumption against registration by sustaining the burden of proving: "(1) In the case of a pesticide which meets or exceeds the criteria for risk set forth in paragraphs (a)(3) (i) or (iii) that when considered with the formulation, packaging, method of use, and proposed restrictions on and directions for use and widespread and commonly recognized practices of use, the anticipated exposure to an applicator or user and to local, regional or national populations of nontarget organisms is not likely to result in any significant acute adverse effects; or (ii) in the case of a pesticide which meets or exceeds the criteria for risk set forth in paragraph (a)(3)(ii) that when considered with proposed restrictions on use and widespread and commonly recognized practices of use, the pesticide will not concentrate, persist, or accrue to levels in man or the environment likely to result in any significant chronic adverse effects; or (iii) that the determination by the Agency that the pesticide meets or exceeds any of the criteria for risk was in error." A primary purpose of the RPAR is to screen for appropriate action those pesticide uses which pose risks which are of sufficient concern to require the Agency to consider whether offsetting benefits justify the risks. Accordingly, the Agency's approach to rebuttal determinations concentrates on whether the risk concerns which are central to each RPAR proceeding have in fact been answered.

[3] On January 31, 1978, the Administrator of the Agency classified all uses of endrin for restricted use and limited them to use by or under the direct supervision of certified applicators (40 CFR 162.31; 43 FR 5788, February 9, 1978). The uses were classified under the Agency's Optional Procedures for Classification of Pesticide Uses by Regulation (40 CFR 162.30; 42 FR 44170, September 1, 1977). All uses of endrin will remain so classified for restricted use unless and until such time as they may be unconditionally cancelled.

public. If the Secretary of Agriculture comments in writing within 30 days of receiving the Notice, the Agency is required to publish the Secretary's comments and the Administrator's response to those comments, together with the Notice. The statute also requires the Administrator to submit notices issued pursuant to section 6 to a Scientific Advisory Panel (SAP) for comment on the impact of the proposed action on health and the environment, at the same time and under the same procedures as those described for review by the Secretary of Agriculture [section 25(d)].

Although not required to do so under the statute, the Agency decided that it is consistent with the general theme of the RPAR process and the Agency's overall policy of open decision-making to afford an opportunity to registrants and other interested persons to comment on the bases for the proposed action during the time that the proposed action is under review by the Secretary of Agriculture and the SAP. Accordingly, the Preliminary Notice and PD 2/3 were made available to registrants and other interested persons at the time the decision documents were transmitted for formal external review. (The Preliminary Notice was published in the **Federal Register**; interested persons were notifed that PD 2/3 was available through publication of a Notice of Availability in the **Federal Register** and by other means.) Registrants and other interested persons were allowed the same period of time to comment, 30 days, that the statute provides for receipt of comments from the Secretary of Agriculture and the SAP. The Agency considered comments received after this date, to the extent it was possible to do so, consistent with orderly decision-making.

III. Determinations and Announcement of Regulatory Actions

As detailed in the Preliminary Notice and PD 2/3, the Agency considered information on the risks associated with the uses of endrin, including information submitted by registrants and other interested persons in rebuttal to the endrin RPAR. The Agency also considered information on the social, economic, and environmental benefits of the uses of endrin subject to the RPAR, including benefits information submitted by registrants and other interested persons in conjunction with their rebuttal submissions, and information submitted by the United States Department of Agriculture. The Agency's assessment of the risks and benefits of the uses of endrin subject to this RPAR, its conclusions and determinations on whether any uses of endrin pose unreasonable adverse effects on the environment, and its determination on whether modifications in terms or conditions of registration reduce risks sufficiently (as an alternative to cancellation) to eliminate any unreasonable adverse effects, were summarized in the Preliminary Notice and set forth in detail in PD 2/3. PD 2/3 was adopted by the Agency as its Statement of Reasons for the determinations and actions announced in the Preliminary Notice and as its analysis of the impacts of the proposed regulatory actions on the agricultural economy.

This Notice constitutes the Agency's Final Notice of Determination Concluding the Endrin RPAR. It reflects modifications in the Agency's initial determinations on the risks, benefits, and unreasonable adverse effects of the uses of endrin which the Agency has concluded are appropriate after review of the comments and information received concerning PD 2/3 and the Preliminary Notice from the Secretary of Agriculture, the SAP, and other sources. This Notice also reflects the modifications in the regulatory actions announced in the Preliminary Notice which the Agency has concluded are appropriate, in light of the comments and other information received on PD 2/3 and the Preliminary Notice from all sources. PD 4, which accompanies this Notice, discusses in detail the information that was received [4] and the Agency's reasons for changing or not changing its initial determinations and the regulatory actions announced in the Preliminary Notice. Finally, this Notice announces the regulatory actions which the Agency is implementing concerning endrin. The Agency hereby incorporates PD 2/3 and PD 4 as its Statement of Reasons for these actions.

A. Determinations on Risks

The endrin RPAR was based on information indicating that endrin posed the following risks to humans and the environment: (1) Oncogenicity; (2) fetotoxic and teratogenic effects; (3) fatalities to endangered species; (4) significant population reductions in non-target organisms; (5) acute toxicity to wildlife; and (6) acute hazards to humans and domestic animals through dermal exposure.

As PD 2/3 explained, the Agency determined, based on the RPAR record, that the weight of the evidence on oncogenicity indicates that endrin is unlikely to pose an oncogenic risk to humans. Moreover, the Agency determined that the risk presumptions for acute dermal toxicity and fatalities to endangered species had been rebutted.[5] As PD 2/3 also explained, the Agency determined that information submitted during the RPAR was insufficient to remove the Agency's concerns that endrin causes significant population reductions in non-target organisms, that it poses a risk of acute toxicity to wildlife and that it poses a risk of acute toxicity to wildlife and that it poses a risk of teratogenicity to humans. The Agency concluded that these risks are associated, to differing degrees, with most uses of endrin and are of sufficient magnitude to require the Agency to determine whether the uses of endrin offer offsetting social, economic or environmental benefits.

B. Determinations on Benefits

The uses of endrin which are subject to this Notice fall into four categories: cotton uses; small grains uses; apple orchard uses; and other uses.[6]

1. *Cotton Uses.* Endrin is used on cotton crops, principally for control of the cotton bollworm and the tobacco budworm. For this use, endrin is formulated almost exlusively in combination with methyl parathion, endrin serving as an adjuvant to methyl parathion. Endrin is a minor cotton insecticide, and its use has declined in recent years as resistance to it has become widespread in some areas.

Numerous alternative pesticides are registered with EPA for control of the cotton bollworm and tobacco budworm, and several of the alternatives are at least as efficacious as, and less hazardous than, the endrin-methyl parathion formulation.

The Agency has determined that the use of endrin on cotton provides small benefits to users and no benefits to any other group. Cancellation of this use would cause current endrin users to use

[4] The comments received from the SAP and the Secretary of Agriculture are attached as Appendices to PD 4. All other comments are available for public inspection in the endrin public file.

[5] In connection with its evaluation of the risk presumption relating to endangered species, the Agency consulted with the United States Fish and Wildlife Service (FWS) pursuant to section 7 of the Endangered Species Act of 1973, 16 U.S.C. 1531. The FWS has expressed its biological opinion that the continued use of endrin in accordance with the regulatory actions initiated by the Preliminary Notice is not likely to "jeopardize the continued existence" of threatened or endangered species, nor to result in the destruction or adverse modification of their critical habitats. The biological opinion of the FWS is attached as an Appendix to PD 4.

[6] The category of "other uses" comprises: sugarcane; seed treatments for conifers, watermelons and vegetables; alfalfa and clover seed crops; ornamentals; tree paint; and perch treatments for controlling birds.

alternative pesticides whose cost per acre treatment would not be significantly greater than endrin's and whose use over a growing season might increase growers' production costs by an aggregate amount on the order of $1 million.

2. *Small Grains Uses.* Endrin's use to control the army cutworm and the pale western cutworm on wheat provides substantial benefits to growers. No federally-registered alternative pesticides are available for control of the pale western cutworm, and the Agency has concluded that, if uncontrolled, the pale western cutworm would damage crops sufficiently to reduce wheat yields by 4.7 million bushels annually. Although this would have a minor impact on total United States wheat production, it would reduce the gross revenues of endrin users by approximately $15 million annually. Alternative pesticides are available to control the army cutworm, but they are more expensive than endrin. Endrin users' production costs would increase by an aggregate of approximately $1.2 million annually if alternatives were used.

3. *Apple Orchard Uses.* Endrin is applied as a post-harvest ground spray to control voles (mice) in many apple-producing areas. Alternative pesticides are available but they do not provide the same level of control as endrin for certain pests. The replacement of endrin with zinc phosphide, the only federally-registered interstate pesticide whose efficacy is comparable to endrin's, would result in a 6.7% annual loss in apple production on the acreage currently treated with endrin. This loss of production would reduce annual revenues of producers now using endrin by approximately $5.3 million. The replacement of endrin with chlorophacinone and diphacinone, pesticides registered for use in certain apple-producing states, would result in a 3.3% annual loss in apple production on the acreage currently treated with endrin. This loss of production would reduce revenues of producers now using endrin by approximately $2.4 million. The Agency has determined that production losses of this magnitude would cause the price of apples to increase.

4. *Other Uses.* The Ageny has determined that virtually no benefits are associated with the uses of endrin on sugarcane to control the sugarcane borer and on ornamentals. The Agency has determined that some benefits are associated with the following uses of endrin: seed treatments for conifers, watermelons and vegetables; tree paint; and perch treatments for controlling birds. The Agency has determined that some potential benefits are associated with the use of endrin on alfalfa and clover seed crops and on sugarcane to control the sugarcane beetle.

C. Determinations on Unreasonable Adverse Effects

The Agency has made the following unreasonable adverse effect determinations with respect to the uses of endrin subject to this RPAR:

1. *Determinations on Cotton Uses.* The Agency has determined that the use of endrin on cotton in all areas east of Interstate Highway #35 (including all states east of the Mississippi River, Arkansas, Louisiana, Missouri, and portions of Texas and Oklahoma) poses risks which are greater than the social, economic and environmental benefits of the use. Accordingly, the Agency has determined that the use of endrin on cotton crops in these areas will generally cause unreasonable adverse effects on the environment, when used in accordance with widespread and commonly recognized practice.

The Agency has also determined that risks of the use of endrin on cotton in areas west of Interstate Highway #35 are greater than the social, economic and environmental benefits of these uses unless risk reductions are accomplished by modifications in the terms or conditions of registration, as described below. The Agency has determined, further, that these modifications in the terms or conditions of registration accomplish significant risk reductions and that these risk reductions can be achieved without significant impacts on the benefits of the use. Accordingly, the Agency has determined that, unless these changes in the terms or conditions of registration are accomplished, the use of endrin on cotton in areas west of Interstate Highway #35 will generally cause unreasonable adverse effects on the environment, when used in accordance with widespread and commonly recognized practice, and the labeling of endrin products for use on cotton in those areas will not comply with the provisions of FIFRA.

2. *Determinations on Small Grains Uses.* The Agency has determined that the use of endrin on small grains to control pests other than the army cutworm, the pale western cutworm and grasshoppers poses risks which are greater than the social, economic and environmental benefits of the use. Accordingly, the Agency has determined that these uses of endrin will generally cause unreasonable adverse effects on the environment, when used in accordance with widespread and commonly recognized practice.

The Agency has also determined that the risks of the use of endrin on small grains to control the army cutworm and the pale western cutworm and to control grasshoppers in Montana are greater than the social, economic and environmental benefits of these or conditions of registration, as described below. The Ageny has determined, further, that these modifications in the terms or conditions of registration accomplish significant risk reductions and that these risk reductions can be achieved without signifícnt impacts on the benefits of the uses. Accordingly, the Agency has determined that, unless these changes in the terms or conditions of registration are accomplished, the use of endrin on small grains to control the army cutworm and the pale western cutworm and to control grasshoppers in Montana will generally cause unreasonable adverse effects on the environment, when used in accordance with widespread and commonly recognized practice, and the labeling of endrin products for use on small grains to control these pests will not comply with the provisions of FIFRA.

3. *Determinations on Apple Orchard Uses.* The Agency has determined that the use of endrin in apple orchards in Eastern States for control of meadow voles poses risks which are greater than the social, economic and environmental benefits of the use. Accordingly, the Agency has determined that this use of endrin will generally cause unreasonable adverse effects on the environment, when used in accordance with widespread and commonly recognized practice.

The Agency has also determined that the risks of the use of endrin in apple orchards in Eastern States for control of the pine vole and in apple orchards in Western States for control of meadow voles are greater than the social, economic and environmental benefits of these uses, unless risk reductions are accomplished by modifications in the terms or conditions of registration, as described below. The Agency has determined, further, that these modifications in the terms or conditions of registration accomplish significant risk reductions and that these risk reductions can be achieved without significant impacts on the benefits of the uses. Accordingly, the Agency has determined that, unless these changes in the terms or conditions of registration are accomplished, the use of endrin in apple orchards in Eastern States to control the pine vole and in apple

orchards in Western States to control meadow voles will generally cause unreasonable adverse effects on the environment, when used in accordance with widespread and commonly recognized practice, and the labeling of endrin products for use on apple orchards to control these pests will not comply with the provisions of FIFRA.

4. *Determinations on Other Uses.* a. *Sugarcane.* The Agency has determined that the use of endrin on sugarcane to control the sugarcane borer poses risks which are greater than the social, economic and environmental benefits of the use. Accordingly, the Agency has determined that this use of endrin will generally cause unreasonable adverse effects on the environment, when used in accordance with widespread and commonly recognized practice.

The Agency has also determined that the risks of the use of endrin on sugarcane to control the sugarcane beetle are greater than the social, economic and environmental benefits of this use, unless risk reductions are accomplished by modifications in the terms or conditions of registration, as described below. The Agency has determined, further, that these modifications in the terms or conditions of registration accomplish significant risk reductions and that these risk reductions can be achieved without significant impacts on the benefits of the use. Accordingly, the Agency has determined States to control the pine vole and in apple orchards in Western States to control meadow voles will generally cause unreasonable adverse effects on the environment, when used in accordance with widespread and commonly recognized practice, and the labeling of endrin products for use on apple orchards to contol these pests will not comply with the provisions of FIFRA.

4. *Determinations on Other Uses.* a. *Sugarcane.* The Agency has determined that the use of endrin on sugarcane to control the sugarcane borer poses risks which are greater than the social, economic and environmental benefits of the use. Accordingly, the Agency has determined that this use of endrin will generally cause unreasonable adverse effets on the environment, when used in accordance with widespread and commonly recognized practice.

The Agency has also determined that the risks of the use of endrin on sugarcane to control the sugarcane beetle are greater than the social, economic and environmental benefits of this use, unless risk reductions are accomplished by modifications in the terms or conditions of registration, as described below. The Agency has determined, further, that these modifications in the terms or conditions of registration accomplish significant risk reductions and that these risk reductions can be achieved without significant impacts on the benefits of the use. Accordingly, the Agency has determined that, unless these changes in the terms or conditions of registration are accomplished, the use of endrin on sugarcane to control this pest will generally cause unreasonable adverse effects on the environment, when used in accordance with widespread and commonly recognized practice, and the labeling of endrin products for use on sugarcane to control this pest will not comply with the provisions of FIFRA.

b. *Ornamentals.* The Agency has determined that the use of endrin on ornamentals poses risks which are greater than the social, economic and environmental benefits of the uses. Accordingly, the Agency has determined that these uses of endrin will generally cause unreasonable adverse effects on the environment, when used in accordance with widespread and commonly recognized practice.

c. *Conifer Seeds; Alfalfa and Clover Seed Crops; Tree Paint.* The Agency has determined that the risks of the uses of endrin on conifer seeds, on alfalfa and clover seed crops (in Colorado), and as tree paint (in Texas) are greater than the social, economic and environmental benefits of these uses, unless risk reductions are accomplished by modifications in the terms or conditions of registration, as described below. The Agency has determined, further, that these modifications in the terms or conditions of registration accomplish significant risk reductions and that these risk reductions can be achieved without significant impacts on the benefits of the uses. Accordingly, the Agency has determined that, unless these changes in the terms or conditions of registration are accomplished, these uses of endrin will generally cause unreasonable adverse effects on the environment, when used in accordance with widespread and commonly recognized practice, and the labeling of endrin products for these uses will not comply with the provisions of FIFRA.

d. *Bird Perch Treatments.* The Agency has determined that the use of endrin in unenclosed bird perch treatments poses risks which are greater than the social, economic and environmental benefits of the use. Accordingly, the Agency has determined that this use of endrin will generally cause unreasonable adverse effects on the environment, when used in accordance with widespread and commonly recognized practice.

The Agency has also determined that the risks of the use of endrin in "Rid-A-Bird" and other enclosed bird perch treatments are greater than the social, economic and environmental benefits of this use, unless risk reductions are accomplished by modifications in the terms or conditions of registration, as described below. The Agency has determined, further, that these modifications in the terms or conditions of registration accomplish significant risk reductions and that these risk reductions can be achieved without significant impacts on the benefits of the uses. Accordingly, the Agency has determined that, unless these changes in the terms or conditions of registration are accomplished, the uses of endrin in "Rid-A-Bird" and other enclosed bird perch treatments will generally cause unreasonable adverse effects on the environment, when used in accordance with widespread and commonly recognized practice, and the labeling of endrin products for this use will not comply with the provisions of FIFRA.

D. Announcement of Regulatory Actions

Based upon these determinations (developed in detail in PD 2/3 and PD 4), the Agency is initiating the following regulatory actions, and this document shall constitute its Notice of Intent regarding these actions:

1. Cancellation and denial of registrations of endrin products for use on cotton in all areas east of Interstate Highway #35 (including all states east of the Mississippi River, Arkansas, Louisana, Missouri, and portions of Texas and Oklahoma).

Cancellation and denial of registrations of endrin products for use on cotton in areas west of Interstate Highway #35 unless registrants or applicants for registration modify the terms or conditions of registration as follows: Modification of the label of endrin products for use on cotton in areas west of Interstate Highway #35 to add the following:

For use in areas west of Interstate Highway #35 only.

Required Clothing for Female Workers

Female ground applicators, mixers and loaders and flagpersons must wear long-sleeved shirts and long pants made of a closely woven fabric, and wide-brimmed hats. Mixers and loaders must also wear rubber or synthetic rubber-boots and aprons.

Warning to Female Workers

The United States Environmental Protection Agency has determined that endrin causes birth defects in laboratory animals. Exposure to endrin during pregnancy should be avoided. Female workers must be sure to wear all protective clothing and use all protective equipment specified on this label. In case of accidental spills or other unusual exposure, cease work immediately and follow directions for contact with endrin.

Equipment

Ground Application.—For use with boom-nozzle ground equipment. Apply at not less than 5 gallons total mixture, water and chemical, per acre. Do not use nozzle liquid pressure at greater than 40 psi (pounds per square inch). Do not use cone nozzle size smaller than 0.16 gallons per minute (gpm) at 40 psi such as type D2–25 or TX–10, or any other atomizer or nozzle giving smaller drop size.

Aerial Application.—Do not apply at less than 2 gallons total mixture of water and chemical per acre. Do not operate nozzle liquid pressure over 40 psi (pounds per square inch) or with any fan nozzle smaller than 0.4 gallons per minute (gpm) or fan angle greater than 65 degrees such as type 6504. Do not use any cone type nozzles smaller than 0.4 gpm nor whirl plate smaller than #46 such as type D4–46 or any other atomizer or nozzle giving smaller drop size. Do not release this material at greater than 10 feet height above the crop.

Application Restrictions

Do not apply this product within ⅛ mile of human habitation.

Do not apply this product by air within ¼ mile or by ground within ⅛ mile of lakes, ponds, or streams. Application may be made at distances closer to ponds owned by the user but such application may result in excessive contamination and fish kills.

Do not apply when rainfall is imminent.

Apply only when wind velocity is between 2 mph and 10 mph.

Procedures To Be Followed if Fish Kills Occur or if Ponds are Contaminated

In case of fish kills, fish must be collected promptly and disposed of by burial. Ponds in which fish kills have occurred, and user-owned ponds exposed to endrin by application at distances closer than otherwise prohibited, must be posted with signs stating: "Contaminated: No Fishing." Signs must remain for one year after a fish kill has occurred or for six months after lesser contamination unless laboratory analysis shows endrin residues in the edible portion of fish to be less than 0.3 parts per million (ppm).

Prophylactic Use

Unnecessary use of this product can lead to resistance in pest populations and subsequent lack of efficacy.

2. Cancellation and denial of registration of endrin products for use on small grains to control all pests other than the army cutworm, the pale western cutworm and grasshoppers. Cancellation and denial of registration of endrin products for use on small grains for control of the army cutworm, the pale western cutworm and grasshoppers unless registrants or applicants for registration modify the terms or conditions of registration as follows:

Modification of the label of endrin products for use on small grains to control the army cutworm, the pale western cutworm and grasshoppers to add the following:

Required Clothing for Female Workers

Female ground applicators, mixers and loaders and flagpersons must wear long-sleeved shirts and long pants made of a closely woven fabric, and wide-brimmed hats. Mixers and loaders must also wear rubber or synthetic rubber boots and aprons.

Warning to Female Workers

The United States Environmental Protection Agency has determined that endrin causes birth defects in laboratory animals. Exposure to endrin during pregnancy should be avoided. Female workers must be sure to wear all protective clothing and use all protective equipment specified on this label. In case of accidental spills or other unusual exposure, cease work immediately and follow directions for contact with endrin.

Equipment

Ground application.—For use with boom-nozzle ground equipment. Apply at not less than 5 gallons total mixture, water and chemical, per acre. Do not use nozzle liquid pressure at greater than 40 psi (pounds per square inch). Do not use cone nozzle size smaller than 0.16 gallons per minute (gpm) at 40 psi such as type D2–25 or TX–10, or any other atomizer or nozzle giving smaller drop size.

Aerial application.—Do not apply at less than one gallon total mixture of water and chemical per acre. Do not operate nozzle liquid pressure over 40 psi (pounds per square inch) or with any nozzle smaller than 0.4 gallons per minute (gpm) or fan angle greater than 65 degrees such as type 6504. Do not use any cone type nozzles smaller than 0.4 gpm nor whirl plate smaller than #46 such as type D4–46 or any other atomizer or nozzle giving smaller drop size. Do not release this material at greater than 10 ft. height above the crop.

Application Restrictions

Do not apply this product within ⅛ mile of human habitation.

Do not apply this product by air within ¼ mile or by ground within ⅛ mile of lakes, ponds or streams. Application may be made at distances closer to ponds owned by the user but such application may result in excessive contamination and fish kills.

Do not apply when rainfall is imminent.

Apply only when wind velocity is between 2 mph and 10 mph.

Procedures To Be Followed if Fish Kills Occur or if Ponds are Contaminated

In case of fish kills, fish must be collected promptly and disposed of by burial. Ponds in which fish kills have occurred, and user-owned ponds exposed to endrin by application at distances closer than otherwise prohibited, must be posted with signs stating: "Contaminated: No Fishing." Signs must remain for one year after a fish kill has occurred or for six months after lesser contamination unless laboratory analysis shows endrin residues in the edible portions of fish to be less than 0.3 part per million (ppm).

Pests for Which This Product May Be Applied

This product may be applied to control the following pests only: army cutworm; pale western cutworm; grasshoppers. [*NOTE:* currently grasshoppers may *only* be included on endrin products for use in Montana only.]

3. Cancellation and denial of registration of endrin products for use in apple orchards in Eastern States to control meadow voles.

Cancellation and denial of registration of endrin products for use in apple orchards in Eastern States to control the pine vole and in Western States to control meadow voles unless registrants or applicants for registration modify the terms or conditions of registration as follows:

Modification of the label of endrin products for use in apple orchards in Eastern States to control the pine vole

and in Western States to control meadow voles to add the following:

Required Clothing for Female Workers

Female applicators, mixers and loaders must wear long-sleeved shirts and long pants made of a closely woven fabric, and wide-brimmed hats. Mixers and loaders must also wear rubber or synthetic rubber boots and aprons.

Warning to Female Workers

The United States Environmental Protection Agency has determined that endrin causes birth defects in laboratory animals. Exposure to endrin during pregnancy should be avoided. Female workers must be sure to wear all protective clothing and use all protective equipment specified on this label. In case of accidental spills or other unusual exposure, cease work immediately and follow directions for contact with endrin.

Application Restrictions

Do not apply this product within 50 feet of lakes, ponds or streams.

Do not apply this product within 50 feet of areas occupied by unprotected humans.

Do not apply when rainfall is imminent.

Procedures To Be Followed if Fish Kills Occur

In case of fish kills, fish must be collected promptly and disposed of by burial. Ponds in which fish kills have occurred must be posted with signs stating: "Contaminated: No Fishing." Signs must remain for one year after a fish kill has occurred unless laboratory analysis shows endrin residues in the edible portion of fish to be less than 0.3 parts per million (ppm).

Equipment

Apply by ground equipment only.

Use a very coarse spray with minimum pressure necessary to penetrate ground cover. Do not apply as a fine spray. Power air blast equipment must be modified to meet the above application restriction. Consult the State recommendations for acceptable methods of adapting equipment.

Prophylactic Use

Unnecessary use of this product can lead to resistance in the vole population and subsequent lack of efficacy.

Pests for Which This Product May Be Applied

This product may be applied to control the following pests only:

Eastern United States—Pine Vole (Microtus pinetorum)
Western United States—Meadow Voles (Microtus species)

4. Cancellation and denial of registration of endrin products for use on sugarcane to control the sugarcane borer. Cancellation and denial of registration of endrin products for use on sugarcane to control the sugarcane beetle unless registrants or applicants for registration modify the terms or conditions of registration as follows:

Modification of the label of endrin products for use on sugarcane to control the sugarcane beetle to add the following:

Required Clothing for Female Workers

Female applicators, mixers and loaders must wear long-sleeved shirts and long pants made of a closely woven fabric, and wide-brimmed hats. Mixers and loaders must also wear rubber or synthetic rubber boots and aprons.

Warning to Female Workers

The United States Environmental Protection Agency has determined that endrin causes birth defects in laboratory animals. Exposure to endrin during pregnancy should be avoided. Female workers must be sure to wear all protective clothing and use all protective equipment specified on this label. In case of accidental spills or other unusual exposure, cease work immediately and follow directions for contact with endrin.

Application Restrictions

Apply only with low-pressure ground equipment. Cover furrows with soil promptly after application.

Pests for Which This Product May Be Applied

This product may be applied only to control the sugarcane beetle.

5. Cancellation and denial of registration of endrin products for use on ornamentals.

6. Cancellation and denial of registration of endrin products for use for conifer seed treatments unless registants or applicants for registration modify the terms or conditions or registration as follows:

Modification of the label of endrin products for use for conifer seed treatments to add the following:

Application Restrictions

Do not sow treated seed when large numbers of migratory birds are expected.

7. Denial of registration of endrin products for use as tree paint unless applicants for registration modify the terms or conditions or registration as follows:

Modification of the label of endrin products for use as tree paint to add the following:

Required Clothing for Female Workers

Female workers handling or applying this product must wear long-sleeved shirts and long pants made of a closely woven fabric, wide-brimmed hat, and rubber or synthetic rubber boots and aprons.

Warning to Female Workers

The United States Environmental Protection Agency has determined that endrin causes birth defects in laboratory animals. Exposure to endrin during pregnancy should be avoided. Female workers must be sure to wear all protective clothing and use all protective equipment specified on this label. In case of accidental spills or other unusual exposure, cease work immediately and follow directions for contact with endrin.

8. Denial of registration of endrin products for use on alfalfa and clover seed crops unless applicants for registration modify the terms or conditions of registration as follows:

Modification of the lable of endrin products for use on alfalfa and clover seed crops to add the following:

Required Clothing for Female Workers

Female ground applicators, mixers and loaders and flagpersons must wear long-sleeved shirts and long pants made of a closely woven fabric, and wide-brimmed hats. Mixers and loaders must also wear rubber or synthetic rubber boots and aprons.

Warning to Female Workers

The United States Environmental Protection Agency has determined that endrin causes birth defects in laboratory animals. Exposure to endrin during pregnancy should be avoided. Female workers must be sure to wear all protective clothing and and use all protective equipment specified on this label. In case of accidental spills or other unusual exposure, cease work immediately and follow directions for contact with endrin.

Equipment

Ground Application—For use with boom-nozzle ground equipment. Apply at not less than 5 gallons total mixture, water and chemical, per acre. Do not use nozzle liquid pressure at greater than 40 psi (pounds per square inch). Do not use cone nozzle size smaller than 0.16

gallons per minute (gpm) at 40 psi such as type D2–25 or TX–10, or any other atomizer or nozzle giving smaller drop size.

Aerial Application—Do not apply at less than 2 gallons total mixture of water and chemical per acre. Do not operate nozzle liquid pressure over 40 psi (pounds per square inch) or with any fan nozzle smaller than 0.4 gallons per minute (gpm) or fan angle greater than 65 degrees such as type 6504. Do not use any cone type nozzles smaller than 0.4 gpm nor whirl plate smaller than #46 such as type D4–46 or any other atomizer or nozzle giving smaller drop size. Do not release this material at greater than 10 feet height above the crop.

Application Restrictions

Do not apply this product within ⅛ mile of human habitation.

Do not apply this product by air within ¼ mile or by ground within ⅛ mile of lakes, ponds or streams. Application may be made at distances closer to ponds owned by the user but such application may result in excessive contamination and fish kills.

Do not apply when rainfall is imminent.

Apply only when wind velocity is between 2 mph and 10 mph.

Procedures To Be Followed if Fish Kills Occur or if Ponds are Contaminated

In case of fish kills, fish must be collected promptly and disposed of by burial. Ponds in which fish kills have occurred, and user-owned ponds exposed to endrin by application at distances closer than otherwise prohibited, must be posted with signs stating: "Contaminated: No Fishing." Signs must remain for one year after a fish kill has occurred or for six months after lesser contamination unless laboratory analysis shows endrin residues in the edible portion of fish to be less than 0.3 parts per million (ppm).

9. Denial of applications for registration of endrin for use in unenclosed bird perch treatments.

Cancellation and denial of applications for registration of endrin for use in "Rid-A-Bird" and other enclosed bird perch treatments unless registrants or applicants for registration modify the terms or conditions of registration as follows:

Modification of the label of endrin products for use in enclosed bird perch treatments to add the following:

Required Clothing for Female Workers

Female workers handling this product must wear long-sleeved shirts and long pants made of a closely woven fabric, wide-brimmed hats, and rubber or synthetic rubber aprons.

Warning to Female Workers

The United States Environmental Protection Agency has determined that endrin causes birth defects in laboratory animals. Exposure to endrin during pregnancy should be avoided. Female workers must be sure to wear all protective clothing and use all protective equipment specified on this label. In case of accidental spills or other unusual exposure, cease work immediately and follow directions for contact with endrin.

Special Warning

Do not use within one mile of roosting sites or within two miles of nesting sites of peregrine falcons, as identified by the United States Fish and Wildlife Service.

IV. Procedural Matters

This Notice initiates actions to cancel unconditionally the registrations of the following uses of endrin: use on cotton in all areas east of Interstate Highway #35; use on small grains to control all pests other than the army cutworm, the pale western cutworm and grasshoppers; use on apple orchards in Eastern States to control meadow voles; use on sugarcane to control the sugarcane borer; and use on ornamentals. This Notice also notifies applicants for new registrations of these uses of endrin, as well as applicants for registration of endrin for use on unenclosed bird perch treatments, that these applications are denied.

This Notice also initiates actions to cancel the registrations of the following uses of endrin unless registrants modify the terms and conditions of registration as required by this Notice: use on cotton west of Interstate Highway #35; use on small grains to control army cutworms and pale western cutworms; use on apple orchards in Eastern States to control the pine vole and use on apple orchards in Western States to control meadow voles; use on sugarcane to control the sugarcane beetle; use for conifer seed treatment; and use in enclosed bird perch treatments. This Notice also notifies applicants for new registrations of these uses of endrin, as well as applicants for registration of endrin for use as tree paint (in Texas), for use on alfalfa and clover seed crops (in Colorado), and for use on small grains to control grasshoppers (in Montana), that these applications are denied unless they are corrected to include the terms and conditions of registration specified in this Notice.

Under Sections 6(b) and 3(c) of FIFRA, applicants, registrants and other interested or affected parties may request a hearing on the cancellation and denial actions that this Notice initiates. This Section of the Notice explains how affected persons may request a hearing, and the consequences of requesting or failing to request a hearing in accordance with the procedures specified in this Notice.

A. Procedures for Requesting a Hearing

1. *Deadline for requesting a hearing on the cancellation actions.* (a) Registrants affected by the cancellation actions initiated by this Notice may request a hearing on *specific registered uses* of endrin within 30 days of receipt of this Notice, or on or before [30 days from publication], whichever occurs later. (b) Any other person adversely affected by the cancellation actions initiated by this Notice may request a hearing on *specific registered uses* of endrin on or before [30 days from publication].

2. *Deadline for requesting a hearing on the denial actions.* Applicants for new registration of the uses affected by the denials announced in this Notice may request a hearing *on specific uses* of endrin within 30 days of receipt of this Notice, or on or before [30 days from publication], whichever occurs later. Other interested persons may request a hearing with the concurrence of the applicant during the time period available to the applicant.

3. *How to request a hearing.* All registrants, applicants, and other interested or affected parties who request a hearing must file the request in accordance with the Agency's Rules of Practice Governing Hearings (40 CFR Part 164). These procedures specify, among other things, that: 1) all requests for a hearing must be accompanied by objections that are specific for *each use* for which a hearing is requested [40 CFR 164.20(b)] and 2) that all requests must be *received* by the Hearing Clerk within the applicable thirty (30) day time period [40 CFR 164.5(a)]. Failure to comply with these requirements will automatically result in denial of the request for a hearing.

Requests for hearings must be submitted to: Hearing Clerk (A–110), U.S. Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460.

B. Consequences of Filing or Failing To File a Hearing Request

1. *Consequences of filing a timely and effective hearing request.* If a hearing on the Administrator's cancellation or

denial of registration of a specific use or uses of endrin is requested in a timely and effective manner, the hearing will be governed by the Agency's Rules of Practice for Hearings under FIFRA Section 6 (40 CFR Part 164). In the event of a hearing, the cancellation and denial actions subject to the hearing will not become effective except pursuant to orders of the Administrator at the conclusion of the hearings.

2. *Consequences of failure to file in a timely and effective manner.* If a hearing on the Administrator's unconditional cancellation or denial of registration of any specific use of endrin is not requested in accordance with the procedures specified above within the applicable 30-day time period, cancellation or denial of registration of the specific use of endrin becomes final and effective at the end of the 30-day period.

If a hearing on the Administrator's conditional cancellation or denial of registration of any specific use of endrin is not requested in accordance with the procedures specified above within the applicable 30-day time period, the Agency, immediately after the 30-day period, will notify registrants and applicants of the procedures to be followed to amend their registrations and applications for registration in order to include the terms and conditions of registration specified in this Notice. That notification will establish the date(s) on which the cancellations and denials will become effective unless the registrants and applicants have applied to amend their registrations or their applications for registrations to include the terms and conditions of registration specified in this Notice, and will provide other necessary instructions and information.

Dated: July 17, 1979.

Steven D. Jellinek,

Assistant Administrator for Toxic Substances.

Appendix A—Federal Insecticide, Fungicide,and Rodenticide Act (FIFRA) Scientific Advisory Panel

Review of Notice of Determination Concluding the Rebuttable Presumption Against Registration (RPAR) of Pesticide Products Containing Endrin

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel has completed review of plans by the Environmental Protection Agency (EPA) for initiation of regulatory action on endrin pesticide products under the provisions of Section 6(b) of FIFRA as amended. The review was completed after open meetings were conducted in Arlington, Virginia, during the periods of October 26–27, 1978, and December 14–15, 1978.

Maximum public participation was encouraged during formal review of all aspects of the conclusion of the RPAR on endrin. **Federal Register** notices announcing meetings in October and December were published in the **Federal Register** on October 16, 1978, and October 30, 1978, respectively. In addition, telephonic calls and special mailings were sent to the general public who had previously expressed an interest in activities of the Panel. Written statements relative to regulatory action on endrin were received over a period of several weeks from the Velsicol Chemical Corporation, and expert witnesses which submitted documents in behalf of the Velsicol Chemical Corporation; the Cooperative Extension Service of New York State; U.S. Department of Interior; the Environmental Defense Fund; Dr. Melvin Reuber, pathologist; Dr. Elizabeth L. Anderson, Executive Director, Carcinogen Assessment Group of EPA; and EPA technical staff. In addition, oral comments were received from EPA staff, USDA staff, members of the pesticide industry, EDF, Extension Service of New York State, and the general public.

In consideration of all matters brought out during Panel meetings, matters detailed in written and oral statements, and careful study of all documents submitted by the Agency, the Panel submits the following report on endrin:

The FIFRA Scientific Advisory Panel is especially indebted to Dr. Melvin Reuber of Columbia, Maryland, and Dr. Roy Albert of the EPA Carcinogen Assessment group for their forthright scientific debate on the potential carcinogenicity of endrin.

Aside from the exceptions noted below the Scientific Advisory Panel agrees with the Agency's proposed course of action for the continued registration of endrin as outlined in Endrin Position Document 2/3, submitted to the Panel on October 19, 1978:

(1) The required label changes for the continued registration of endrin for the control of pale western and army cutworms and grasshoppers should include a ¼ mile distance restriction from human habitation so as to more adequately protect humans from exposure.

(2) The Agency should actively seek to find alternate means to endrin for the safe and effective control of pine and western meadow voles.

(3) The required label changes for the continued registration of endrin for pine and western meadow vole control and as a conifer seed treatment should include a geographic restriction in accordance with the report received from the Director of the Fish and Wildlife Service so that endangered species may be adequately protected.

(4) The Panel is concerned with the risks inherent with the prophylactic use of endrin and urges that the Agency reexamine the label statements regarding such use.

(5) The Panel wishes to reiterate its concern with the lack of adequate pesticide monitoring data and the importance of such data in evaluating health impacts. In the case of endrin we are particularly concerned about the lack of such data both for endrin and 12-keto-endrin, a major toxic metabolite.

For the Chairman.

Dated: December 19, 1978.

H. Wade Fowler, Jr.,

Executive Secretary, FIFRA Scientific Advisory Panel.

Appendix B

Department of Agriculture,
Office of the Secretary,
Washington, D.C. November 22, 1978.

Hon. Douglas M. Costle (A–100),
Administrator, U.S. Environmental Protection Agency, Washington, D.C.

Dear Mr. Costle: This is the United States Department of Agriculture's response to the U.S. Environmental Protection Agency's (EPA) Notice of Determination pursuant to 40 CFR 162.11(a)(5), concluding the Rebuttable Presumption Against Registration (RPAR) on endrin, and EPA's proposed intent to cancel and/or modify the terms and conditions of registration, pursuant to Section 6(b)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The notice, dated October 23, 1978, indicates EPA is proposing to (a) cancel certain uses of endrin, and (b) retain certain uses with label modifications.

The U.S. Department of Agriculture and State Cooperators, under the National Agricultural Pesticide Impact Assessment Program (NAPIAP), have been pleased to interact with EPA in developing informational materials upon which the proposed EPA regulatory action is based. We are also pleased to have the opportunity to review the Notice of Determination and the accompanying position document. We are dedicated to mutual resolution of problems involving actual health risks to the consumer and the applicator or farm worker as well as adverse effects on the environment.

We concur that endrin should be classified as a restricted use pesticide and, thus, applied only by or under the supervision of certified applicators. We commend EPA for selecting regulatory options that are consistent with the biological and economic assessments. These include retaining uses in all States on small grains for the pale western cutworm, *Agrotis orthogonia* (Morrison), the army cutworm, *Euxoa auxiliaris* (Grote), and for grasshoppers; in apple orchards for the pine vole, *Microtus pinetorum,* and the western meadow vole, *Microtus montanus;* on sugarcane for the sugarcane beetle, *Eutheola rugiceps* (Le Conte); for seed treatment of conifers, watermelons, vegetables, and melons; in alfalfa and clover seed crop production; use as a tree paint; and the perch treatment for nuisance bird control. We also agree with the continued use of endrin for control of cotton pests in areas where there is a low potential for aquatic contamination.

However, the Department has several issues of concern relative to the regulatory options proposed as follows:

1. We question the advisability of requiring protective clothing for all female workers. The teratogenic risk, as defined, should apply only to female workers capable of bearing children.

2. It would seem appropriate in aerial applications that the wind velocities be

stated only as to the maximum miles per hour allowed rather than a range. We further believe that flying heights be consistent for all crops. A range of wind velocities and varable flying height limitations will pose operational difficulties for aerial applicators that do not appear to be warranted.

3. The use of the word "only" in identifying the vole species to be controlled in apple orchards may cause unnecessary enforcement problems when more than one species is established in an orchard. We assume that the destruction of eastern meadow voles incidental to the control of pine voles would not be considered inconsistent with labeling. Also, we do not believe the statement on prophylactic use adds anything to the usefulness of the label information and should be deleted.

4. We are concerned that the decisionmaking process employed by EPA in evaluating minor use patterns may result in cancellations without adequate justification. For example, it is being proposed that the use of endrin for chinch bug control in small grains be cancelled because only limited benefit data was presented. A similar situation occurred in the chlorobenzilate Notice of Determination regarding Arizona citrus, and minor uses on deciduous fruits and nuts. These actions do not seem to be consistent with the intent of the RPAR process for analyzing benefits and risks. It would seem more logical and highly desirable to retain these minor uses until an unreasonable adverse effect can be clearly demonstrated.

5. We believe the cancellation of uses on cotton in the Southeast and the Delta will have limited economic impact at the present time. However, a number of entomologists in the cotton producing States have pointed out that the use of endrin on cotton could become critical if current alternative pesticides are lost through the regulatory process, reduced market availability, or become less effective. As indicated in our November 4, 1976 report, on page 5–18, these entomologists requested the use of endrin on cotton be retained in Alabama, Arkansas, Mississippi, Florida, Georgia, and New Mexico. It is not clear why a one-quarter mile buffer requirement would be inadequate in the Southeast and delta States. Data presented to EPA by Dr. Virgil Freed (Oregon State University) and the current use experience in Arkansas seems to clearly indicate that a one-quarter mile buffer is adequate in all geographic areas.

It has been almost two years since the States provided use and benefit data. Because changes may have occurred in pest management strategies, we have contacted all States for any new information that may be available. This will be forwarded to you if and when received.

In summary, we concur with the proposed restrictions on the use of endrin for cotton and other crops, with one major exception. We believe endrin should be available to Southeast and Delta cotton producers using the one-quarter mile buffer restriction. We are confident EPA will give favorable consideration to our suggestions and recommendations in developing the final registration determinations. The opportunity to have cooperated on this important agricultural matter is very much appreciated.

Please let us know if additional information would be helpful.

Sincerely,

Bob Bergland,

Secretary.

Appendix C–1

U.S. Department of the Interior,
Fish and Wildlife Service,
Washington, D.C., December 11, 1978.

In reply refer to: FWS/OES 375.0.

Mr. Douglas M. Costle,
Administrator, Environmental Protection Agency, 401 M Street SW., Washington, D.C.

Dear Mr. Costle: This responds to your November 8, 1978, request for reinitiation of consultation under Section 7 of the Endangered Species Act of 1973 on the use of the pesticide endrin relative to its impact on Endangered and Threatened species. This biological opinion should be considered as an extension of my biological opinion of June 8, 1978, a copy of that opinion is enclosed for your information.

The species considered in this opinion are the same as those considered in the June 8, 1978, opinion with the addition of the American peregrine falcon (*Falco peregrinus anatum*).

Our June 8, 1978, opinion concluded that pesticide products containing endrin are not likely to jeopardize the continued existence of the listed species considered in the opinion, or result in the destruction or adverse modification of their Critical Habitats provided the Environmental Protection Agency (EPA) develop new label restrictions designed to reduce the likelihood of exposing endangered species to endrin and that EPA reinitiate Section 7 consultation prior to final action involving new label restrictions.

The EPA has developed new regulatory actions for endrin and this document represents the U.S. Fish and Wildlife Service's Biological Opinion on these new regulatory actions. This opinion will follow the format established in our June 8, 1978, opinion.

Fish and Mollusks

In my June 8, 1978, opinion I stated that although there is currently no evidence to indicate that Threatened or Endangered species are being exposed to toxic amounts of endrin under existing use restrictions, it is apparent that if Threatened or Endangered fish species are exposed to toxic amounts of endrin it is likely that their continued existence could be jeopardized or their Critical Habitats destroyed or modified. Therefore, it was recommended that EPA develop new label restrictions which would put more stringent controls on the use of endrin to reduce the potential of introducing endrin into the aquatic ecosystems of Threatened or Endangered fish and mollusks.

The EPA has responded to this recommendation by canceling the use of endrin on cotton in all areas east of Interstate Highway #35; by adding use restrictions to the cotton, small grain and alfalfa and clover seed crops labels prohibiting use within one-fourth mile of streams, lakes or ponds (except ponds owned by the users in cotton applications), prohibiting use when rainfall is imminent and when wind velocity is greater than ten miles per hour; by requiring aerial applications of endrin be released at no greater altitude than 19 feet above the crop for cotton and 10 feet above the crop for small grains and alfalfa and clover seed crops; by prohibiting application within 50 feet of lakes, streams or ponds and prohibiting use when rain is imminent for orchard control of pine and western meadow volves; by requiring use of low pressure ground equipment and prompt covering of furrows with soil after application for sugarcane beetle control; and by canceling all ornamental uses of endrin. These additional use restrictions are anticipated to significantly reduce the potential for introducing endrin into the aquatic ecosystems of Threatened or Endangered species of fish and mollusks. Therefore, it is my biological opinion that the use of endrin under these proposed label restrictions is not likely to jeopardize the continued existence of threatened species of fish and mollusks or adversely modify their Critical Habitats.

Birds

My June 8, 1978, opinion indicated that exposure of Threatened or Endangered birds to endrin could occur from direct application but would normally be expected to occur through drift from aerial applications or from feeding in areas contaminated from run-off after application. The EPA's new proposed use restrictions for endrin, as cited above, alleviate our concern for adverse impact to Threatened and Endangered birds via drift and run-off during and after endrin usage.

Secondary poisoning of Threatened or Endangered birds is a potential problem which EPA has addressed through labeling on the cotton, small grain, orchard, and alfalfa and clover seed crop uses by requiring prompt burial of fish, if fish kills are experienced. Strict adherence to the requirement will eliminate the potential of secondary poisoning to brown pelicans and will significantly reduce the potential for secondary poisoning of bald eagles and peregrine falcons.

The use of endrin treated conifer seeds offers the potential for secondary kill if seed-eating birds are incidentally poisoned by feeding on the treated seed. Peregrine falcons and bald eagles may prey upon impacted birds and secondary poisoning could possibly ensue. The EPA has addressed this potential problem by prohibiting applications when large numbers of migratory birds are expected.

The use of endrin for pine vole and western meadow vole control in orchards offers the potential for secondary poisoning to the bald eagle and peregrine falcon. Orchards generally have large populations of birds and rabbits, as well as other animals. When birds and rabbits are adversely impacted by endrin they become prime targets for raptors such as the bald eagle and peregrine falcon. If eagles or peregrines consume endrin poisoned birds,

rabbits or other small mammals, secondary poisoning may ensue.

Since endrin is used only after harvest, the areas of impact for Artic peregrine falcons would be their major wintering areas. The major wintering area is defined in my previous opinion. These wintering areas generally are not in the range of the target species, however, the potential for exposure still exists. The area of potential impact on bald eagles and American peregrine falcons would be those areas in which eagles and falcons are known to nest and feed. More specific information on these sites may be obtained from the Fish and Wildlife Service Regional Directors.

Therefore, it is my biological opinion that the use of endrin for pine vole and western meadow vole control in orchards is likely to jeopardize the continued existence of the Arctic peregrine falcon, the American peregrine falcon and the bald eagle when used in their normal ranges.

The proposed registration actions concerning Sorbikill and Rid-a-Bird are not likely to impact the endangered species being considered in this opinion. Therefore, it is my biological opinion that the cancellation of Sorbikill and label changes for Rid-a-Bird are not likely to jeopardize the continued existence of Threatened or Endangered species or adversely modify their Critical Habitat.

The proposed label restrictions, as discussed in the fish and mollusks section, will significantly reduce the potential hazard of endrin to the whooping crane, Attwater's prairie chicken and Mississippi sandhill crane. Therefore, it is my biological opinion that the use of endrin under the proposed label restrictions is not likely to jeopardize the continued existence of the whooping crane, Mississippi sandhill crane and Attwater's prairie chicken or adversely modify their Critical Habitats.

Cumulative Effects

Endrin is a chlorinated hydrocarbon. As such, it has the potential to cause sublethal reproductive impairment in birds. Much of the population decline of bald eagles and peregrine falcons is attributed to reproductive impairment caused by the contamination of their food supply by chlorinated hydrocarbons. Thus, any increase in chlorinated hydrocarbon contamination of bald eagle, American peregrine falcon and Arctic peregrine falcon food supplies must be considered a contributory factor to their decline. The use of endrin in areas where bald eagles and peregrine falcons may feed, as described above, must be considered inconsistent with their conservation and thus contributing to a situation which may jeopardize the continued existence of these species.

Reasonable and Prudent Alternatives

The use of endrin in orchards for control of pine voles and western meadow voles should be prohibited in the wintering habitat of the Arctic peregrine falcon (defined above) and in American peregrine falcon and bald eagle nesting and feeding ranges. The changes should be relatively easy to make because of the very limited distribution of pine voles and western meadow voles in the areas of concern. The Fish and Wildlife Service (FWS) will be available to define these ranges.

Conclusion and Recommendations

Based on review of the above information and other information and data available to the Service, it is my biological opinion that the registration actions and labeling restrictions proposed by EPA for the use of endrin on cotton, small grains, sugarcane, ornamentals, conifer seeds, tree paint, Sorbikill and Rid-a-Bird are not likely to jeopardize the continued existence of the listed species considered herein or result in destruction or adverse modification of their Critical Habitats. The proposed registration actions and label restrictions for the use of endrin in orchards is likely, through cumulative effects, to jeopardize the continued existence of the bald eagle (*Haliaeetus leucocephalus*), American peregrine falcon (*Falco peregrinus anatum*), and Arctic peregrine falcon (*Falco peregrinus tundrius*) unless use restrictions are expanded as stated in the alternative section above or in a similar fashion. The orchard use is not likely to jeopardize the continued existence of the other listed species considered herein or result in destruction or adverse modification of their Critical Habitats.

Sincerely yours,

Lynn A. Greenwalt,

Director.

Appendix C–2

United States Department of the Interior,
Fish and Wildlife Service,
Washington, D.C. 20240.

March 8, 1979.

In Reply Refer To:
FWS/OES 375.4

Mr. Douglas M. Costle, Administrator
U. S. Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460.

Dear Mr. Costle: This responds to your November 8, 1978, request for reinitiation of consultation under Section 7 of the Endangered Species Act of 1973 on the use of the pesticide endrin relative to its impact on Endangered and Threatend species and their habitats.

Based upon conversations with your representatives at a January 10, 1979, meeting, subsequent conversations with your representatives and the receipt of additional information on bald eagle wintering areas, present and historic peregrine falcon range and restoration sites, laboratory data, field observations and the location of apple orchards, which was not available for my biological opinion of December 14, 1978, I have revised my biological opinion relative to the orchard use of endrin and its impact on the Endangered bald eagle *(Haliaeetus leucocephalus),* Arctic peregine falcon *(Falco peregrinus tundrius)* and American peregrine falcon *(Falco peregrinus anatum).* My biological opinion relative to other uses of endrin and other Endangered or Threatened species remains unchanged. A copy of that opinion is enclosed for your information.

As stated in the biological opinion, the use of endrin for pine vole and western meadow vole control in orchards offers the potential for secondary poisoning to the bald eagle and peregrine falcon. Individuals in the State of Washington suspect that endrin sprayed in orchards is poisoning waterfowl, quail, chukar partridges and songbirds. This has not been well documented by laboratory analyses and the extent of the problem remains undefined. Laboratory analysis of a male kestrel found dead in an orchard in Washington in 1976 indicated levels of endrin in the lipid sufficient to suspect endrin poisoning as the cause of death. The source of the endrin is unknown. The State of New York made an effort to determine the environmental effects of endrin used for orchard mouse control in the late fall and winter of 1977–78. The studies included the monitoring of wildlife, soil, water, and fish. Unfortunately, the laboratory analyses have not been completed and the final results of the monitoring are not yet available.

Bald eagles do not normally winter in eastern apple areas. The nearest concentration of wintering eagles to apple areas occurs in Sullivan County, New York. Western apple areas, however, do contain populations of wintering bald eagles. This is particularly true of the Columbia River and its tributaries. A food habits study being conducted in the State of Washington indicates that in one area (Wells Pool) coot and other birds were the most important food items during the winter of 1977–78. In another area (Chief Joseph Pool) chukar partridges were the most important food items. Both of these locations are in the orchard areas of the state. As previously stated, endrin used in orchards is suspected of poisoning waterfowl and partridges in the State of Washington. Lab analyses have so far failed to satisfactorily substantiate this suspicion. Therefore, the potential for secondary poisoning cannot be considered a real threat.

Based on the above information, it is my biological opinion that the use of endrin for pine vole and western meadow vole control in orchards is not likely to jeopardize the continued existence of the bald eagle.

The current and historic range of the American peregrine falcon in the western part of the county does not overlap areas of commercial apple production in Washington and Idaho. American peregrines in the eastern part of the county were extirpated in the 1950's and early 1960's primarily because of the effects of environmental contaminants. In recent years, attempts have been made to reintroduce peregrine falcons to thier former range in the Northeast. Several of the reintroduction sites are in the general proximity of commercial apple orchards. Endrin was used in New York State, in the vicinity of one of the release sites, during the winter of 1977–78. To date, there has been no indication of conflict between this use and the peregrine reintroduction program, but final results of New York State's monitoring program are not yet available.

Based on the above information, it is my biological opinion that the use of endrin for pine and western meadow vole control in orchards is not likely to jeopardize the

continued existence of the American peregrine falcon.

My opinion of December 14, 1978, expressed concern for the Arctic peregrin falcon where its wintering habitat ovelaps the range of the pine vole. From subsequent information provided by your representatives, I have learned that apples are not commercially grown in that overlapping area, therefore, endrin is not likely to be used in apple orchards in the wintering habitat of Arctic peregrines. Based on this information, it is my biological opinion that the use of endrin for pine and meadow vole control in apple orchards is not likely to jeopardize the continued existence of the Arctic peregrine falcon.

Cumulative Effects

My biological opinion of December 14, 1978, expressed the concern that endrin, being a chlorinated hydrocarbon, had the potential to accumulate in the food chains of bald eagles and peregrin falcons to levels that could cause sublethal reproductive impairment. Additional discussions with experts concerning the metabolic breakdown of endrin in avian species and levels throught to produce reproductive impairment in avian species have allayed my fears. Thus, while much of the population decline of bald eagles and peregrine falcons is attributed to reproductive impairment caused by the contamination of their food supply by chlorinated hydrocarbons, it is not believed that the use of endrin in apple orchards will contribute to the reproductive impairment experienced by these species.

Conclusions and Recommendations

Based on review of the above information and other information and data available to the Service, it is my biological opinion that the use of the pesticide endrin in apple orchards for control of pine and western meadow voles is not likely to jeopardize the continued existence of the bald eagle, American peregrine falcon, or Arctic peregrine falcon. If, however, new information indicating a possible effect, either direct or indirect, or on any Endangered species becomes available (either from the New York State monitoring program or the State of Washington, or any other source) consultation must be reinitiated.

Sincerly yours,

Lynn A. Greenwalt,

Director.

Enclosure.

Endrin—Position Document 4

Special Pesticide Review Division,
Office of Pesticide Programs, Office of Toxic Substances, U.S. Environmental Protection Agency.

Acknowlegements

Writing Staff

Kyle R. Barbehenn, Project Manager, SPRD, OPP

EPA Project Support Team

Mitchell Bernstein, Attorney, OGC
William Burnam, Pharmacologist, HED, OPP
David Coppage, Aquatic Biologist, HED, OPP
George Ludvik, Entomologist, BFSD, OPP
Dudley Mattson, Economist, BFSD
David Severn, Chemist, HED, OPP

EPA Pesticide Chemical Review Committee (PCRC)

Dr. William A. Wells, Chairperson, SPRD, OPP
Dr. Elizabeth L. Anderson, CAG, ORD
Dr. Richard N. Hill, OTS
Dr. Allen L. Jennings, SRD, OPM
Dr. Donna R. Kuroda, OHEE, ORD
Mr. John J. Neylan, PED, OE
Mr. Michael S. Winer, OGC

Table of Contents

I. Introduction
II. Analysis of Comments
A. Comments Relating to Risk
1. Teratogenicity
2. Acute Toxicity to Wildlife
3. Population Reductions of Aquatic Organisms
4. Fatality to Endangered Species
5. Oncogenicity
B. Comments Relating to Benefits
1. Cotton
2. Small Grains
3. Apple Orchards
C. Comments Relating to Regulatory Options
1. Designation of Target Species in Apple Orchards
2. Equipment
3. Distance Restrictions from Aquatic Habitats
4. Distance Restrictions from Human Habitation
5. Posting of Contaminated Ponds
6. Teratogenic Warning
7. Protective Clothing for Workers
8. Warnings on Prophylactic Use
9. Enforcement
10. Grasshopper Control
11. Conifer Seed Treatment
D. Comments Relating to Procedural Matters
1. Availability of the Agency's Rebuttal Analysis
2. Use of Relevant Information on Risk Assessment
3. Development of State Programs for Use on Cotton
III. Conclusions
A. Registration for Use on Cotton
1. Warning to Female Workers
2. Aerial Application
3. Application Restrictions
4. Procedures to be Followed if Fish Kills Occur
B. Registration for Use of Small Grains
C. Registration for Use in Apple Orchards
D. Registrations for Use on Sugarcane
E. Registration for Treatment of Conifer Seed
F. Registration for Use as Tree Paint
G. Registration of Use on Alfalfa and Clover Seed Crops
H. Registration for Use in Enclosed Bird Perch Treatments
Bibliography
Appendices
A. Comments by the Scientific Advisory Panel
B. Comments by the U.S. Department of Agriculture
C. Comments by the U.S. Fish and Wildlife Service

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA) [7 U.S.C. Section 136 *et seq.*] regulates all pesticide products. Section 6(b) of FIFRA authorizes the Administrator of the Environmental Protection Agency ("EPA" or the "Agency") to issue a notice of intent to cancel the registration of a pesticide or to change its classification if it appears to him that the pesticide or its labeling "does not comply with the provisions of [FIFRA] or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment."

The Agency designed the Rebuttable Presumption Against Registration (RPAR) process to gather risk and benefit information about problem pesticides and to make balanced decisions concerning them in a manner which allows all interested groups to participate. This process is set forth in 40 CFR 162.11.

On July 27, 1976, the Agency issued an RPAR notice for pesticide products containing endrin (41 FR 31316). The endrin RPAR was one of the first issued by the Agency. At the time it was issued, Agency RPAR procedures were still in a formative stage, and a detailed Position Document 1 did not accompany the endrin RPAR notice. Copies of this Document, however, were provided to all registrants and other concerned parties.

On October 20, 1978, the Agency issued Endrin: Position Document 2/3 (EPA, 1978; hereinafter called PD 2/3), and published a Notice of Determination and Availability of the Position Document in the **Federal Register** on November 2, 1978 (43 FR 51132). In PD 2/3 the Agency analyzed the rebuttals it received in response to the original RPAR notice, presented its analysis of both the risks and benefits associated with the uses of endrin, and proposed a decision to conclude the RPAR process.

FIFRA requires the Agency to submit notices issued pursuant to Section 6 to the Secretary of Agriculture ("Secretary" or "USDA") for comment on the impact of the proposed action on the agricultural economy [Section 6(b)] and to a Scientific Advisory Panel (SAP) for comment on the impact of the

proposed action on health and the environment [Section 25(d)]. The Agency is required to submit these documents to the Secretary and the SAP at least 60 days before making the final notice effective by sending it to registrants and making it public. The Secretary and the SAP may comment in writing within 30 days of receiving the notice; the Agency is required to publish any of their comments and the Administrator's responses with publication of the final notice.

Additionally, since the RPAR notice indicated that endrin had caused fatality to an endangered species, the Agency was required by Section 7 of the Endangered Species Act of 1973 (16 U.S.C. 1531; see also 50 CFR Part 402, 43 FR 870) to initiate formal consultation with the U.S. Fish and Wildlife Service, U.S. Department of the Interior ("FWS"). The biological opinion submitted to the Agency by the FWS on June 8, 1978 requested the Agency to take appropriate action to reduce risks to endangered species from the use of endrin and to reinitiate formal consultation on the proposed actions (Greenwalt, 1978a). The comments of the FWS to the actions proposed in PD 2/3 were made on Devember 14, 1978 and in a supplementary revision on March 1, 1979 (Greenwalt, 1978b; 1979).

The Agency is not required under the statute to afford registrants and other interested persons an opportunity to comment on the bases for the proposed action while it is under review by USDA and the SAP. However, the Agency decided that it was consistent with the purpose of the RPAR process and the Agency's overall policy of open decisionmaking to do so. Accordingly, PD 2/3 solicited such public comments.

The Agency has received a number of public comments in response to the November 2, 1978 Notice of Determination and the Endrin PD 2/3. Responses from the SAP, USDA, the FWS, Velsicol Chemical Corporation ("Velsicol"), which is the sole manufacturer of endrin in the United States, the Environmental Defense Fund (EDF), and other interested parties have been analyzed and are addressed in Section II of this document. The entire responses from the SAP, USDA and the FWS are contained in the Appendices to this PD 4.

II. Analysis of Comments

A. Comments Relating to Risk

1. *Teratogenicity.* Comments have been received regarding the validity of the tests on which the Agency relied in concluding that endrin has a teratogenic potential, regarding levels of exposure that can reasonably be anticipated, and regarding a margin of safety (MOS) that can be considered as "ample". These comments and the Agency's response are:

a. *Validity of the Tests.* The Agency's risk analysis (PD 2/3) noted that a single exposure of 5 mg/kg endrine on the eighth day of pregnancy caused significant numbers of meningoencephaloceles in hamsters. A no-observed-effect-level (NOEL) of 1.5 mg/kg was established by this study (Chernoff et al., 1978a). Although the teratogenic studies were discussed at length in the FIFRA–SAP Meeting of October 26, 1978 (Transcript of Proceedings, hereinafter referred to as SAP, date, page) the SAP did not make a formal comment on this issue. A consultant for Velsicol seemingly challenged the validity of the Chernoff study (Velsicol, Exh. 31) but the points raised were rebutted by Chernoff et al. (1978b). Velsicol's second consultant accepted the validity of the NOEL of 1.5 mg/kg (Velsicol, Exh. 30, p. 6). Since Velsicol and its first consultant now apparently accept the validity of the established NOEL for purposes of risk assessment (Velsicol, p. 38 and Exh. 61) the details of the related comments and rebuttal do not require further discussion.

b. *Levels of Exposure that can be Anticipated.* The Agency's exposure analysis focused on dermal exposure to bystanders and persons associated with the process of applying endrin and on the ingestion of contaminated fish. The Agency believes that dermal exposure to applicators and bystanders can be reduced adequately by requiring protective clothing, prohibiting application within specified distances from human habitation and similar measures less stringent than cancellation. Ingestion exposure, however, is of particular concern to the Agency because the contamination of fish-bearing waters by runoff is difficult to control, especially where endrin is used on cotton in areas which receive substantial rainfall.

Velsicol has challenged the validity of the Agency's estimate of potential exposure from the consumption of contaminated fish. The Agency based its risk assessment on the consumption of 250g of fish containing 1.0 ppm endrin. This level of exposure was conceived, not as a "worst case" estimate, but as a reasonable one (SAP, October 26, 1978, p. 14). Velsicol did not challenge the use of 250g but contends that 0.4 ppm is the highest concentration of endrin that can be expected to occur in fish (Velsicol, p. 39 and Exh. 5) and relies on the National Pesticide Monitoring Program (NPMP, Seabolt, 1978) results to support its contention.

It is true that the highest concentration of endrin in fish reported for 1977 in the NPMP was 0.4 ppm. However, the NPMP samples fish from major rivers throughout the nation without regard to sources of potential contamination. Moreover, the sampling program is not designed to determine maximum residues that might occur in fish in cropland areas. NPMP samples from Alabama, Arkansas, Louisiana, Mississippi and Tennessee were taken in major rivers where cotton is grown on only a small fraction of the drainage area; where only a small fraction of the cotton that is grown is actually treated with endrin (EPA, 1977); and without regard to actual or potential runoff episodes. Thus, it is somewhat surprising to find endrin present at any concentrations in the fish sampled. The widespread and regular occurrence of endrin in these fish is strong evidence that endrin is likely to be present in much higher concentrations in fish more closely associated with cotton culture.

Levels of endrin in the edible portion of catfish killed by endrin may in fact exceed 4 ppm (Mount and Putnicki, 1966). Since the record establishes that fish kills have been associated with the use of endrin, especially on cotton, it can reasonably be expected that fish-bearing waters have been contaminated with sub-lethal doses of endrin with a much greater frequency. Velsicol's consultant (Velsicol, Exh. 5) has estimated that fish exposed to sub-lethal doses of endrin could accumulate as much as 2.0 ppm. Thus, the Agency's use of 1.0 ppm endrin as a concentration that could reasonably be anticipated in fish consumed by humans is on firm ground.[1]

What must be anticipated in the field is a wide range of endrin residue levels in fish that vary in the probability of occurrence—from the infrequent but very high levels associated with dead and dying fish through all degrees of sub-lethally exposed fish. The amounts of such fish that may be consumed in a day may range widely from small (125 g) through large (250 g) to exceptional portions (500 g). Ranges in the margins

[1] Velsicol also relies on estimates of runoff concentrations which would allegedly occur if a quarter-mile barrier strip were to be imposed to show that the resulting concentrations would be "safe" for fish and apparently for residues in the fish (Velsicol p. 26; Exh. 24). As discussed more fully in Section II C 3, the Agency cannot rely upon their calculations and assumptions involved in the barrier strip model and cannot reasonably conclude that residue levels would be acceptable under that proposal.

of safety associated with these variables will be presented below.

c. *Adequacy of the Margin of Safety (MOS).* The Agency has no rule of general applicability for determining the ampleness of the teratogenic margin of safety associated particular compounds—each chemical is evaluated individually. In evaluating endrin the Agency noted that humans might be 50 times more sensitive to the convulsive effects of endrin than are hamsters and concluded that such a difference in sensitivity might also be true for teratogenic effects (PD 2/3, p. 51). Thus, the Agency concluded that exposure levels that would give rise to an MOS of 500 or lower would be cause for concern. Both the SAP (SAP, October 26, 1979, pp. 30–32) and Velsicol (Velsicol, p. 40 and Exh. 32) objected to the derivation of this MOS. Informally, the SAP members indicated that an ample MOS should be somewhere between 100 and 1000 but could arrive at no scientific method for establishing an appropriate value (SAP, October 26, 1979, pp. 28–34, 124–126). No formal recommendation was made.

Velsicol has attempted to make several points bearing on the assessment of teratogenic risk that require a clarifying response:

(1) Velsicol claims tht the "actual" NOEL lies somewhere between the lowest observed effect level (5 mg/kg) and the observed NOEL (1.5 mg/kg) (Velsicol, pp. 41–2, Footnote (FN 7). This contention is merely speculative. The Agency must rely on established values in estimating the MOS.

(2) Velsicol argues that an MOS of 100 is appropriate for endrin. Velsicol states "As Dr. Wilson notes (Exhibit 32), and as the Agency Acknowledges (Position Document 2/3, p. 51), However, a margin of safety of 100 is normally ample for low potential environmental teratogens such as pesticides* * * " (Velsicol, p. 40). The Agency has neither characterized pesticides in general nor endrin specifically as "low potential environmental teratogens". Further, what the Agency did say concerning the adequacy of margins of safety was:

> While the Agency has not established official guidelines for determing the adequacy of the MOS for teratogens in general, Agency toxicologists believe that an MOS below 100 would be a matter of serious concern. Interpreting these values, however, requires a judgement based on other factors associated with characteristics of the chemical, routes of exposure, and the probability of various levels of exposure. thus, the above value should not be construed as an established Agency policy but only as a toxicological guideline for risk assessment against which benefits must be balanced and additional safetly requirements imposed (PD 2/3, p. 50–1).

(3) Velsicol's consultant, Dr. Wilson, has taken exception to the informal comments by the SAP suggesting that an MOS of 1000 might be appropriate. According to Dr. Wilson, "The only reasonable justification for a margin of safety of 1000 would be in the event that endrin were an environmental pollutant of no or negative economic importance and totally without benefit to man. To the contrary, it makes a significant contribution toward providing food and fiber to meet human needs" (Velsicol, Exh. 35). Clearly, Dr. Wilson's concept of the adequacy of an MOS is not cast solely in terms of assessing risk, per se, but is predicated on assumptions concerning environmental pollution and benefits of use. In admitting, however, that a MOS of 1000 may be justified in some circumstances, Dr. Wilson apparently concedes that the teratogenic risk at margins of safety greater than 100 may be cause for concern. [2]

As discussed above, the Agency does take benefits into account in reaching a final regulatory decision concerning a use of a pesticide. Here, the facts that meningoencephalocele is a serious defect and that the benefits from the use of endrin on cotton are very low lead the Agency to conclude that an MO greater than 100 is appropriate for this use of endrin.

(4) Another of Velsicol's arguments implicitly objects to the Agency's use of any MOS at all. Velsicol contends that a pregant woman would have to consume "ludicrously massive amounts of endrin-contaminated fish to incur a teratogenic hazard" (Velsicol, p. 38). Velsicol then goes on to calculate the amount of "maximally contaminated" fish [3] that a pregnant woman would have to consume "in order to incur the threshold teratogenic dose" (Velsicol, p. 39). Presentation of the data in this fashion completely ignores the concept of providing an adequate margin of safety to prevent susceptible persons from ever receiving a "threshold teratogenic dose". The Agency must reject any approach to risk assessment which is premised on the expression of risk in terms of exposure with no margin of safety assoicated with it. Rather, the Agency must exercise its judgement based on the margins of safety which are afforded by the levels of exposure that can reasonably be anticipated.

The following table indicates the teratogenic margins of safety associated with various levels of consumption of contaminated fish by a 60 kg woman:

	Level of consumption (grams)		
	125	250	500
Endrin concentration (ppm):			
0.1	7500	3750	1870
0.5	1500	750	375
1.0	750	375	187
2.0	375	187	93
4.0	187	93	46

The Agency's illustration of a MOS of 375 associated with the consumption of 250 g of fish containing 1.0 ppm endrin (PD 2/3, p. 58) should be put in the context of the total array of possible risk situations rather than isolated as a single point of contention. As indicated in the above table, the lowest MOS that can reasonably be anticipated (46) would result from an oppportunistic harvest of fish in the final throes of endrin toxicity that are consumed in very large quantity, perhaps because refrigeration is lacking. Such a scenario can reasonably be anticipated but may not be a very common event. [4] On the other hand, judging by NPMP data, women consuming fish caught in the major rivers of the Delta region would commonly be exposed to endrin residues but seldom at levels providing an MOS of less than 1,000. Between these two extremes lies an area of intermediate teratogenic risk that is associated with the consumption of fish from many ponds and streams that are contaminated by sublethal levels of endrin because of their proximity to cotton culture. The risks from such exposure must be considered as unreasonable in light of the low benefits associated with the use of endrin on cotton.

2. *Acute Toxicity to Wildlife.* Velsicol (pp. 46–51) has commented as some length on the issue of acute toxicity to wildlife, emphasizing theoretical reasons why the Agency erred in

[2] In fact, Dr. Wilson's reasoning would indicate that an MOS of between 100 and 1000 is appropriate for endrin. Endrin was found in the vast majority of the fish inhabiting all major rivers sampled by the NPMP in Alabama, Arkansas, Lousisana, Mississippi and Tennessee in 1977 (Seabolt, 1978) and it has occurred at lethal or near lethal levels in the brains of brown pelicans, white pelicans and bald eagles (PD 2/3, pp. 37–9). While endrin may not share the apparent ubiquity of certain other organochlorines in the environment, it certainly qualifies as an "environmental pollutant". Further, the value of endrin in protecting the nation's cotton crop, rather than being "significant", is marginal at best.

[3] Velsicol assumes this to be at levels of 0.4 ppm rather than 1 ppm even though the same consultant elsewhere estimates that sublethal doses may result in bioaccumulation as high as 2 ppm.

[4] While pesticides are deliberately used to harvest fish in some parts of the world, it is more reasonable to hypothesize that adults or children may encounter fish in distress from endrin toxicity, may harvest these fish before they are dead, and that pregnant women may consume these fish.

presuming the existence of this risk and noting an absence of confirmatory evidence. Their major argument is that many forms of wildlife will develop an avoidance response from consuming sublethal levels of endrin. The Agency agrees, in principle, that, because of behavioral characeristics, certain individuals or certain species may not be susceptible to poisoning by endrin. On the other hand, the record indicates that wildlife kills have been observed from the use of endrin on wheat in Colorado (Hinkle, 1979); on cotton fields in California and Alabama, and on alfalfa in California (Bushong, 1978). It can reasonably be inferred from these incidents that the foliar application of endrin at any registered dosage has a potential for killing wildlife, despite the theorizing of Velsicol's consultant (Velsicol, Exh. 46). This conclusion is not ameliorated by self-serving allegations of lack of observed effects which are not supported by an appropriate investigation or analysis.[5] The Agency is not aware of adequate surveys conducted by wildlife biologists that demonstrate the absence of adverse effects on wildlife from the use of endrin.

3. *Population Reduction of Aquatic Organisms.* In PD 2/3 the Agency set forth the circumstances surrounding many events that led the Agency to conclude that runoff of endrin has been a major cause of the reported fish kills. Velsicol does not dispute that endrin may have caused fish klls in the past but persists in maintaining that the "reported problems arose from misapplication or misuse of endrin" (Velsicol, p. 45). Velsicol's claims of misuse are purely conjectural and are insufficient to overcome the presumption of risk.[6]

Perhaps the most persuasive evidence that the lethal endrin concentrations associated with many fish kills arose from normal applicaton practices rather than from misuse stems from the association of those incidents with toxaphene as well. Velsicol has asserted that "Toxaphene was idenfified by the Agency as the causal agent in many of the *very same* PERS incidents which earlier had been attributed to endrin" (Velsicol, FN 12, emphasis in original). As noted on PD 2/3 (p. 22), such a coincidence does not serve to exonerate endrin. The frequent coincidence of high concentrations of both endrin and toxaphene, however, is strong circumstantial evidence that the source of both is runoff since it is highly improbable that both endrin and toxaphene were misapplied or misused independently of each other on numerous occasions at the same time and general area. The Agency continues to believe that most fish kills that have resulted from either endrin, toxaphene or both were the result of use consistent with the label. As discussed more fully below, the Agency also remains unconviced that a ¼ mile barrier strip will adequately reduce runoff of these pesticides.

4. *Fatality to Endangered Species.* At the request of the Director of the U.S. Fish and Wildlife Service (Greenwalt, 1978a) the Agency reinitiated Section 7 Consultation prior to determining what final actions to take with respect to endrin. In response, the FWS expressed the opinion, in essence, that most of the Agency's proposed regulatory actions and use restrictions alleviated the FWS' concern for adverse impacts of endrin to threatened and endangered species (Greenwalt, 1978b). An exception made by the FWS was that the use of endrin to control orchard mice was likely to jeopardize the continued existence of the Arctic and American peregrine falcons and the bald eagle when used in the normal ranges of these birds.

At the FIFRA–SAP meeting (SAP, October 26, 1978 pp. 102–3) the Agency's attention was directed to an unpublished manuscript by Stickel et al. (Undated) in which endrin was identified as the cause of death for two bald eagles. This manuscript was not previously available to the endrin RPAR record. The SAP formally recommended that the Agency address the concerns of the FWS by imposing grographical restrictions for the use of endrin in orchards (Fowler, 1978). EDF, relying on the FWS position, proposed cancellation of additional endrin uses (Hinkle, 1979).

Following additional investigations among its staff and consultation with the Agency, however, the FWS revised its position on the use of endrin to control orchard mice, concluding in essence that a case for risk to the Arctic and American peregrine falcons and to bald eagles could not be substantiated by currently available information (Greenwalt, 1979). Accordingly, the FWS concluded that the use of endrin to control voles in orchards is not likely to jeopardize the continued existence of those species. Any new evidence, however, could require a reappraisal of the FWS' opinion.

Velsicol has made several comments on the risks to endangered species (Velsicol, pp. 54–8) that do not affect the Agency's position but which require response.

(1) Velsicol states, "In view of the evidence on the Louisiana brown pelican presented by Velsicol and in view of the conclusion drawn by Director Greenwalt, the Agency has conceded that the endangered species trigger had been rebutted successfully (Position Document 2/3, pp. 33–40)". While the Position Document does in fact conclude that "the risk to endangered species has been rebutted for the brown pelican", the Agency specifically rejected all of Velsicol's arguments as the basis for such a conclusion (PD 2/3, pp. 35–8). Further, the probable fatality to two bald eagles noted in PD 2/3 and the confirmed fatality of two additional bald eagles introduced to the record by the SAP are sufficient to maintain the Agency's concern for that species. However, the Agency has addressed this concern by requiring that fish killed by endrin be collected and buried, thus substantially reducing the most likely source of exposure to bald eagles. With this new requirement, the Agency agrees that the continued use of endrin "is not likely to jeoprarize the continued existence of the bald eagle" (Greenwalt, 1979).

(2) Velsicol cointests the conclusion of the FWS regarding the potential for secondary poisoning of raptors from birds and rabbits that may be exposed to endrin-treated orchards by citing reports submitted by Warren Smith (Velsicol, p. 57, FN 11). As noted above (FN 5) however, Mr. Smith's observations on wildlife do not address the issue. The relevant document on this issue will be the report of the monitoring program conducted in New York in 1977 and this report, as incicated in PD 2/3 (pp. 61–2), is not yet available because chemical analyses are incomplete.

(3) Velsicol cites the opinion of Dr. Howard regarding hazards of secondary poisoning potential to falcons and eagles. However, Velsicol specifically addresses lack of hazard associated with the consumption of orchard mice (Velsicol, p. 58) rather than the non-

[5] For instance, Warren Smith (Velsicol, FN 11) has reported that deer, woodchucks and rabbits continued to thrive a year after orchards in New York were treated with endrin. Deer, however, are browsers unlikely to be feeding extensively on the ground vegetation of orchards, woodchucks should all be in hibernation at the time endrin is applied, and rabbits have a high reproductive potential to compensate for any excessive mortality. Mr. Smith's training is not in the area of wildlife biology and his argument reflects this lack of expertise. Moreover, the report of the monitoring study of these orchards by wildlife biologists is not yet available.

[6] Moreover, Velsicol contends that "the empirical data of sporadic fish kills relied upon by the Agency actually tend to confirm Dr. Freed's theoretical kinetics" concerning runoff potential (discussed more fully in Section II C 3, below) (Velsicol, p. 23). Whether or not this is true, this argument appears to be inconsistent with Velsicol's misuse argument since Dr. Freed's theoretical kinetics are not based on misuse.

target birds and rabbits that are the concern of the FWS.

In summary, the Agency agrees with the revised position of the FWS in concluding that the available evidence does not support the conclusion that the use of endrin is likely to jeopardize the continued existence of peregrine falcons and bald eagles and also concurs that the situation should be reevaluated as new information becomes available. Thus, the available evidence does not require changes in the Agency's position on endangered species.

5. *Oncogenicity.* The Agency's Carcinogen Assessment Group (CAG) analyzed the available evidence on the oncongenicity of endrin and concluded that endrin was unlikely to be a human carcinogen. Accordingly, in PD 2/3, the Agency took the position that the oncongenicity "trigger" had been rebutted. Dr. Melvin Reuber criticized the Agency's conclusion. Dr. Reuber made an oral presentation to the SAP on October 26, 1978 and submitted written comments to the SAP and to the Agency (Reuber, 1978a; b). The CAG has submitted written responses (Anderson, 1978a; b). At the December 14, 1978 SAP meeting, Dr. Reuber and Dr. Roy Albert, Chairman of the CAG, both discussed the issue of endrin's oncogenicity and responded to Panel members' questions.

Dr. Reuber's major points are (1) that most of the oncogenic studies conducted with endrin are invalid for various reasons and the negative findings reported from such studies should receive no weight in assessing the oncogenicity of endrin and (2) that certain of the studies resulted in statistically significant increases in tumors associated with exposure to endrin. The CAG responded that some of the allegedly positive results involved differences of opinion among pathologists. For instance, Dr. Reuber's diagnosis of cerain liver tumors in the FDA rat study could not be confirmed by two other consultant pathologists. Since Dr. Reuber declined an invitation to participate in a joint examination of the slides, the CAG sccepted the opinion of the other pathologiss. While the CAG acknowledged that most of the available studies had some deficiences, it also indicated that all contributed some information and it determined, on balance, that the slight indication of positive endrin effect found in the FDA rat study and the Kettering mouse study was insufficeint to indicate that endrin was likely to be a human carcinogen. (For detailed discussion, see SAP, December 14, 1978).

EDF also commented on the oncogenicity issue at the SAP meeting and in a submission to the Agency (Hinkle, 1979). EDF argues that respectable scientific authority is sufficent evidence upon which the Agency may rely in a determination and that such authority does not have to reflect a majority opinion. EDF alleges that critical questions regarding the endrin studies remain unanswered and, especially in light of Dr. Reuber's diagnosis, the issue of endrin's carcinogenicity remains an open question. Dr. Albert, in response to similar questioning by the SAP, indicated that Dr. Reuber's opinions had been given a great deal of attention by the CAG (SAP, Dec. 14, 1978, p. 35).

Velsicol has also submitted comments on the question of oncogenicity and the Agency must respond to certain of their statements. By incomplete quotation of the NCI Technical Report Series No. 12 (Velsicol, Exh. 48), Velsicol has incorrectly implied that the NCI conclusions were unqualified. Velsicol reported that NCI had concluded that endrin "was not carcinogenic for * * * rats or for * * * mice" (Velsicol, p. 53). The full statement reads, "It is concluded that under the condition of this bioassay, endrin was not carcinogenic for Osborne-Mendel rats or for B6C3F1 mice." By removing the limitations on the conclusion, Velsicol has improperly generalized its applicability. The NCI clearly did not speak to the conclusions of other existing tests, to what might be the case in other strains of rodents, or to how differences in conditions might have affected the outcome of the NCI tests.

Velsicol's comments also incorrectly characterized both the SAP's and the Agency's positions with respect to the oncogenic status of endrin. Velsicol states, "Moreover, the Agency's Scientific Advisory Panel reviewed the evidence of record and concurred in the Agency's conclusion that endrin is not carcinogenic." (Velsicol, p. 53). In fact, the SAP has made no formal comment on the issue and thus has neither concurred in nor dissented from the Agency's conclusion. Moreover, it is the Agency's position only that the weight of the evidence is that endrin is "unlikely to be a human carcinogen" (PH 2/3, p. 44); the Agency has never unqualifiedly concluded that "endrin is not carcinogenic." The Agency recognized that there was some evidence suggestive of oncogenic effects but that the evidence as a whole supported the conclusion that endrin is unlikely to be a human carcinogen. That there was insufficient evidence for the Agency to consider endrin a probable human carcinogen does not mean—as Velsicol suggests—that the Agency has made an unqualified negative finding.

In summary, the Agency has concluded that it is not necessary to modify the determinations set forth in PD 2/3 that endrin is unlikely to be a human carcinogen and that the oncogenicity "trigger" has been rebutted for endrin.

B. Comments Relating to Benefits

1. *Cotton.*—The USDA (Bergland, 1978) comments:

> We believe the cancellation of uses on cotton in the Southeast and Delta will have limited economic impact at the present time. However, a number of entomologists in the cotton producing States have pointed out that the use of endrin on cotton could become critical if current alternative pesticides are lost through the regulatory process, reduced market availability, or become less effective.

In response, the Agency is pleased that the USDA concurs with the Agency's analysis of the present benefits of endrin on cotton which provides the basis for its regulatory decision. If future events indicate a substantial change in the risk/benefit picture, at that time the Agency can reconsider its regulatory decision.

Velsicol has commented extensively on the essentiality of endrin in Integrated Pest Management Programs (IPMP), especially for control of the bollworm complex, and on the economic impact of an endrin cancellation (Velsicol, pp. 60–74). Velsicol states that experts in Alabama, Arkansas, and Mississippi have presented data which indicate that bollworm resistance to endrin in those states is not currently a widespread or major problem (Velsicol, pp. 62 and 66) but that it remains effective on light to moderate infestations. Judicious use of endrin, allegedly, can retard the development of resistance to newer pesticides. Velsicol offers some recent data on treatment costs indicating that a replacement of endrin with the most likely non-RPAR pesticides would result in a total increase in costs of $1,436,116 rather than the Agency's estimate of $717,850.

The Agency's perception of the benefits from the use of endrin on cotton differs only in detail from Velsicol's. The Agency's understanding is that bollworm resistance to endrin per se is virtually complete (Lincoln, 1979; EPA, 1977) and therefore, as Velsicol indicates, endrin is currently formulated for use on cotton mainly in combination with methyl parathion. Moreover, Velsicol admits that the combination is generally efficaceous only for light to moderate infestations. While the Agency concedes that some benefits

could be derived from the use of endrin on cotton, Velsicol's claim of essentiality is hardly supported by the dramatic decline in use in Mississippi, "from approximately 275,000 pounds in 1973 to approximately 75,000 pounds in 1977, and even less in 1978" (Velsicol, Exh. 18). The Agency agrees in principle that the use of a variety of pesticides may be desirable to retard the development of resistance and that endrin could theoretically continue to play some role in IPM programs. Velsicol's claims that endrin is essential for this purpose, however, are not supported by the record.

Velsicol's conclusion that a cancellation of endrin would increase costs by $1.4 million rather than the Agency's estimate of $0.72 million may well reflect current costs of pesticides more accurately than did the Agency's analysis which was based on 1976 values. Even so, the impact projected by Velsicol is probably exaggerated for several reasons. First, Velsicol has eliminated toxaphene and EPN as alternatives because a notice of RPAR has been issued for toxaphene and because EPN is on the pre-RPAR list (Velsicol, p. 68). However, both chemicals are presently available, and it is simply too early to predict whether they will become unavailable at some point in the future. Additionally, Velsicol's analysis fails to account for the reduction in benefits that would result from the regulatory action it would prefer, imposition of a 1/4 mile distance restriction from water (and human habitation) in the states east of Interstate Highway 35 (I–35). Even under Velsicol's analysis, however, its conclusion with regard to endrin's economic importance to the cotton growing industry is remarkably similar to the Agency's and the Agency continues to maintain that endrin is only of minor significance to the cotton industry.

2 *Small Grains.* USDA (Bergland, 1978) has criticized the Agency for an alleged failure to give sufficient consideration to the possible benefits of relatively insignificant uses of endrin for which economic data may be lacking, such as the use of endrin to control chinch bugs. With respect to the use of endrin for chinch bugs, however, public response to the proposed decision set forth in PD 2/3 indicates that the Agency was correct in attributing little or no economic value to endrin. Dr. Leroy Brooks (Kansas), the only proponent of the use, did not renew his appeal for retaining that use after the issuance of PD 2/3, although he submitted other comments to the USDA (Brooks, 1978). No other comments (including those from Velsicol) were received on chinch bugs and the USDA did not specify other uses with respect to which USDA believed the agency incorrectly assessed the benefits of endrin.

Velsicol's comments with regard to the use of endrin on small grains contain factual errors. Regarding Kansas, Velsicol claims that 1,200,000 acres are treated with endrin (presumably for control of pale western cutworm) and, for Oklahoma, 2,000,000 acres are said to be infested and treated for army cutworm (Velsicol, pp. 76–7). These values are inconsistent with the cited references, with the Agency's estimate of usage, and with Velsicol's own production and sales figures. Regarding pale western cutworms in Kansas, Dr. Brooks stated that, "Some localized infestations requiring treatment of 10 to 20 thousand acres occur every two to three years. Large scale outbreaks . . . that would necessitate treatments over a much larger area (possibly up to a million acres) could occur . . ." (Velsicol, Exh. 58). Regarding Oklahoma, Dr. Coppock reported that, "Between five and six million acres of winter wheat were sprayed *for the greenbug* [emphasis added] and army cutworms during that time [1976]" (Coppock, 1976) and Velsicol's estimate can not be derived from that reference. The Agency's estimate for all states combined was an annual average of 416,000 acres for pale western and 691,000 acres for army cutworms. Velsicol's own production estimates indicate a range in usage on small grains from 201,000 pounds in 1976 to 25,000 pounds in 1977 (PD 2/3, p. 6). At 3–4 oz. active ingredient of endrin per acre, these amounts would have treated from a maximum of one million acres in 1976 to a minimum of one hundred thousand acres in 1977. Thus, the Agency's analysis may have overestimated the benefits of endrin's use on small grains somewhat but Velsicol's claims of treated acreage can not be remotely supported by their own production and sales figures, which were provided by Velsicol to provide a more accurate picture of recent usage.

EDF has protested that there are many available substitutes registered for grasshopper control in small grains and rangeland (Hinkle, 1979). However, endrin is not registered for use in rangeland and several of EDF's alternative pesticides are not registered for use on small grains. PD 2/3 (p. 39) incorrectly listed phorate as an alternative since it is recommended as a border treatment in Montana. To clarify the record, the only federally registered alternatives for the use of endrin on wheat are malathion, parathion, methyl parathion and toxaphene.

Velsicol has submitted new data on the efficacy of various insecticides to control grasshoppers in Oklahoma (Coppock and Pitts, undated). The authors concluded that the results of these tests indicate that endrin (as well as malathion, parathion and toxaphene) gave excellent control under the test conditions.

3. *Apple Orchards.* Velsicol's comments on the benefits of endrin's use in apple orchards contains some misplaced criticisms of the Agency's Benefit Analysis (EPA, 1977). Velsicol states that the Agency inappropriately focus upon total apple acres when assessing endrin, and infers that the Agency was naive in not recognizing the "economically disastrous" effects of voles in affected orchards. Velsicol also states that the Agency's national estimates of the effect of an endrin cancellation upon apple supplies is "misleading". Further, Velsicol charges that "the Agency has attempted to minimize the vole problem". Velsicol concludes by asserting that the Agency should have limited its analysis to vole-invested orchards and should have extended the analysis beyond the three-year time horizon presented in the Benefit Analysis (Velsicol, pp. 78–9).

These assertions reflect some misunderstandings about the benefit analysis. The inclusion of the effect of an endrin cancellation upon national apple supplies and prices is neither "misleading" nor an "attempt to minimize the vole problem" but normal Agency procedure. The Endrin Benefit Analysis for Orchards also includes an extensive discussion of producer-level impacts, including analysis of apple losses, production cost changes, farm level prices, and farm revenues. The cost-effectiveness of endrin and various alternative control strategies used by apple growers are also discussed at length. Since the effects of an endrin cancellation may extend beyond current users, the Agency was prudent in *not* limiting the analysis to owners of vole-infested orchards.

With regard to the three-year time horizon used in the report, the Agency is fully aware that impacts could extend beyond this period. However, available data do not permit an accurate assessment of the economic effects likely to occur in the long term (EPA, 1977 pp. 74–5, 80–1, 84–5).

C. Comments Relating to Regulatory Options

1. *Designation of Target Species in Apple Orchards.* USDA (Bergland, 1978) notes, "The use of the word 'only' in identifying the vole species to be controlled in apple orchards may cuase unnecessary enforcement problems when more than one species is established in an orchard. We assume that the destruction of eastern meadow voles incidental to the control of pine voles would not be considered inconsistent with the labeling." Additionally, Dr. Don Hayne (personal communication, Nov. 14, 1978) has noted that the Agency's use of the terms "eastern" and "western" meadow voles has no basis in scientific nomenclature. Dr. Ross Byers (1978) has indicated that the prairie vole (*Microtus ochrogaster*) has behavioral characteristics similar to that of the of the pine vole and that the need for endrin to control this species in the mid-West should be investigated

Having received no additional information, the Agency is unable to address Dr. Byers' concern. The Agency agrees with Dr. Haynes Point. Accordingly, labels for use in apple orchards should designate the pest species as follows:

Eastern United States: Pine Voles *(Microtus pinetorum)*
Western United States: Meadow Voles *(Microtus species)*

The distribution of commercial apple growing areas is such that the broad geographical limits do not pose problems of interpretation.

USDA is correct in its assumption that the destruction of meadow voles incidental to the control of pine voles from the use of endrin in eastern orchards containing both pine voles and meadow voles would not be inconsistent with the label. The use of the word "only" on the label is necessary, however, to preclude the use of endrin where it is intended to control meadow voles rather than pine voles in the East. The presence of pine voles in an orchard in the East may not be used as a pretext for the the use of endrin intended only to control meadow voles.

2. *Equipment.* USDA commented that, for aerial application, wind velocities should be stated as the maximum allowed (i.e. 10 mph) rather than as a range (i.e. 2–10 mph) and that the flying heights should be the same for all crops. Additionally, the State of North Carolina recommended that the label specify "apply only with ground equipment" for use in apple orchards (Blaylock, 1978).

In specifying a minimum wind velocity for aerial application, the Agency is following the recommendation of Velsicol's Expert Panel (Akesson, 1977) and believes that this represents sound advice for controlling drift because it is supported by empirical data relating to conditions and dispersion of drift. The variable height of application referred to by USDA stems from a typographical error. The maximum height for aerial application should be 10 feet above all crops. While it is unlikely that anyone would attempt to control voles by treating apple orchards with endrin by air, such an attempt would be extremely hazardous. Accordingly, such application will be prohibited by a label restriction.

3. *Distance Restriction from Aquatic Habitats.* a. *Cotton Usage East of Interstate Highway 35.* The Agency concluded in the Endrin PD 2/3 that the hazard of endrin to fish arises from transport to water by both drift and runoff. It concluded that a distance restriction can substantially reduce endrin contamination of water resulting from drift, but that no information was available to assess the impact of a distance restriction on the reduction of contamination from runoff. In response to the recommended regulatory option in PD 2/3 to cancel endrin use on cotton east of Interstate Highway 35, Velsicol submitted an extensive discussion defending the efficacy of a ¼ mile restriction from water bodies in diminishing endrin runoff to water in the southeastern United States. The Agency has already engaged in several exchanges of comments on the runoff question with Velsicol and its consultant, both prior to and during the SAP proceedings (Velsicol Exh. 21, 22, 23, 25; Severn, 1978; SAP, October 26, 1978). The Agency will now respond to Velsicol's position on this matter, as developed in its comments on Position Document 2/3 (Velsicol, pp. 17–30). In Velsicol's summary, the following points were made:

(a) Endrin is strongly adsorbed to soil particles at the application site;

(b) Endrin has a "comparatively short residual life" in the environment;

(c) Not more than 1% of applied endrin would be carried to the edge of a treated plot by an intense rainfall;

(d) An intervening ¼ mile of bare cultivated soil would reduce runoff concentrations of endrin to 1% of this 1%, or 0.01% of the amount applied;

(e) Vegetation in the barrier strip would further reduce the runoff by another factor of 10;

(f) Maximum concentration in a pond containing two acre-feet of water resulting from application of 1.25 lbs of endrin to one acre separated from the pond by a barrier strip covered with vegetation would be approximately 2 ppt (parts per trillion);

(g) The efficacy of the distance restriction has been demonstrated by the reduction in fish kills observed in Arkansas after the imposition of a distance restriction;

(h) The acceptability of the distance restriction is also demonstrated by its imposition in Mississippi as part of an emergency exemption for synthetic pyrethroid application to cotton;

(i) Monitoring data from Alabama confirm the efficacy of intervening land in decreasing endrin residues in ponds;

(j) Distance restrictions imposed by the United States Forest Service for pesticide applications in forest areas also support the efficacy of distance restrictions in reducing contamination of adjacent waters; and

(k) In summary, the evidence that a quarter-mile barrier would render endrin runoff from southeastern cotton fields innocuous is overwhelming, and warrants revision of the Agency's preliminary recommendation to cancel the cotton use in the Southeast.

The Agency's response will discuss each of these points in order.

(a) *Adsorption of Endrin to Soil.* The Agency accepts the view put forward by Velsicol that endrin may be strongly bound to soil or suspended sediment. It is generally agreed (Pionke and Chesters, 1973; USDA/EPA, 1976) that compounds which are strongly adsorbed will move mostly on sediment particles. Thus the major mode of runoff transport of endrin is probably through erosion processes.

Since endrin is applied as a foliar spray, rather than directly to the ground, a potential problem appears to be washoff from the foliage soon after application. The record of endrin-related fish kills appears to be correlated with rainfall incidents. Estimates of the amount of pesticide deposited on foliage from aerial application vary, but 50% on foliage and 50% on the ground appears to be a reasonable estimate. Sparr et al. (1966) observed a concentration of endrin in runoff water during a rainfall event seven days after application which was higher than that found during irrigation prior to the rain and stated:

> We believe that this higher endrin concentration resulted from washing the endrin off the foliage.

While there are major flaws in this study (the particulate fraction of the

runoff was apparently not analyzed, although this fraction would be expected to contain most of the endrin, as noted above), the study at least suggests that foliar washoff during a rainfall event is an additional consideration in evaluating the overall extent of endrin transport by runoff.

Another study indicating that foliar washoff of pesticides from cotton makes an important contribution to runoff was recently reported by Willis et al. (1976). These workers applied toxaphene and other pesticides to cotton in a nearly flat watershed equipped with instrumentation to measure surface runoff and sediment and chemical yields at the point where runoff entered a four-acre pond. They found a total of 0.038 lbs/acre of toxaphene in runoff during the period from August to February (a period of low sediment yield); a total of 9 lbs/acre of toxaphene had been applied in August and September. They concluded that the freshly sprayed leaves were an important source of toxaphene in runoff in August and September. These workers also observed that:

> Current cultural practices in the Mississippi Delta may be intensifying sediment and chemical transport from agricultural fields. After harvest, many farmers shred plant residues, till the soil, and form rows. The fields are left with little or no vegetative cover throughout the winter and early spring, and are subject to the erosive forces of rainfall and runoff until adequate cover develops.

Since, as noted above, endrin is bound to soil particles, this study suggests that substantial runoff transport of endrin may occur under current cotton cultural practices.

(b) *Environmental Persistence of Endrin.* Velsicol concluded that endrin has a comparatively short residual life in the environment. Persistence on foliage or soil is an important issue, since the longer a chemical resides at the site of application, the more opportunity there will be for runoff events to occur. The Agency realizes that although persistence is not an important factor for runoff events which occur immediately following application, it can be an important factor in later runoff events.

Velsicol cited studies on endrin photodegradation (Baker and Appelgate, 1974) and soil metabolism (Castro and Yoshida, 1971; Matsumura et al., 1971) in support of its conclusions with regard to endrin persistence. The study by Baker and Applegate used blacklight lamps to irradiate thin films of endrin and other pesticides on glass in the laboratory; they reported a 10–30% photodecomposition of endrin in 20 hours, compared to dark controls. This study has little utility for evaluating the environmental photodegradation of endrin, since it presents no data on the photochemistry of soil-bound endrin. It is likely that bound endrin would be much less accessible to sunlight and in addition might be inherently less photoreactive. The artificial light source employed also makes this study less valid. The claim that mirex was photodegraded suggests that the emission spectrum of the lamps used extended to well below 290 nm (the lower limit of natural sunlight), since mirex has virtually no absorption above 250 nm and no photoreaction could be detected using natural sunlight (Alley et al., 1974). In summary, the information presented by Baker and Applegate may not be used as a reliable indicator of the environmental photodegradation of endrin.

The soil metabolism study of Castro and Yoshida (1971) was performed in flooded and upland soils in the Philippines. Endrin was found to degrade rapidly in a flooded soil but was in fact quite persistent (88% recovered after two months) when the same soil was maintained at 80% of the maximum water-holding capacity.

This study is of dubious utility in evaluating persistence of endrin in the soils of the southeastern United States. A monitoring study performed in 1966 in Greenville, Mississippi (USDA, 1968) found high residues of endrin in soil more than one year after treatment. Soybeans planted in these soils had endrin residues resulting from translocation. While the studies of Matsumura et al. (1971) showed that 25 of 150 soil cultures had the capacity to degrade endrin in laboratory culture, it is clear that endrin can be sufficiently persistent in the southeastern United States to survive a winter season.

(c) *Estimates of Extent of Runoff From Treated Fields.* Velsicol concluded that, as a worst case, not more than 1% of the endrin applied would be carried to the edge of a treated plot by soil erosion. In support of this conclusion, a limited number of controlled runoff studies were cited, in which the total amount of pesticide leaving the field was measured to be less then 1%. However, two recent reviews (Pionke and Chesters, 1973; Leonard et al., 1976) have compiled a much larger number of such runoff studies; the overall range of extent of loss varied from 0.007% to approximately 40%, with 11 studies reporting losses in excess of 1%. These studies encompassed a wide range of conditions (type of pesticide and application conditions, rainfall characteristics, type of soil, crop, slope, etc.), all of which strongly influence runoff, as noted by Velsicol. In addition, a very recent study (Smith et al., 1978) used paraquat as a tracer compound for estimation of sediment transport in a Southern Piedmont watershed. When applied to the soil surface, runoff losses of paraquat commonly exceeded 5%. Although no cover crop was present in this case, it appears that sediment transport of bound pesticides can be a significant source of aquatic contamination. Precise predictions of the behavior of endrin when applied to cotton in the Southeast may not be made based on data currently available. However, based on the studies which are available, the Agency concludes that a 1% runoff yield, while reasonable some of the time, is certainly not a "worst case" since substantially higher values have been observed.

(d) *Efficiency of a Barrier Strip in Reducing Runoff.* The Agency in PD 2/3 concluded that no information was available on which to base a quantitative estimate of the efficacy of intervening land in reducing the runoff potential of endrin. This conclusion derived in part from the observation that quantitative runoff studies (as discussed in (c) above) commonly measured runoff immediately adjacent to the treated field. This point was also made by Velsicol. However, the summary document submitted by Velsicol also states that:

> * * * on the basis of this worst-case runoff model, Dr. Freed calculated that the quarter-mile barrier (assuming it was bare-cultivated) would reduce runoff concentrations of endrin to 1% of what they would be under similar worst-case circumstances with *no* barrier strip * * * (Velsicol, p. 25)

The calculation referred to above is the use of the Universal Soil Loss Equation and a sediment delivery ratio equation to calculate the amount of chemical in overland runoff; the value computed was 0.0127 pounds. The values of the input parameters for the equations are not presented, nor is the manner of carrying out the calculation. In any event, these calculations are not based on any field experiments with endrin, despite Velsicol's contention that detailed data and other information have been provided to the Agency to evaluate endrin runoff.

There is no question but that intervening land areas can have the effect of reducing sediment runoff and thus sediment-bound pesticide transport. However, erosion continues as a major problem; for example, an annual sediment yield of 11.6 tons per

acre was measured on nearly flat land in the Mississippi Delta (Willis et al., 1976). A general equation for the amount of sediment transported overland apparently is not available. Values of the ratio of sediment transported from a specific area by erosion to the amount received by a body of water range from about 0.1 to 0.3 (USDA/EPA, 1975). This report also concluded that:

> The sediment discharged to large rivers is usually less than one-fourth of that eroded from the land surface.

Obviously, this amount will vary with rainfall intensity and previous surface conditions, as well as the distance over which it is transported. A major runoff event may also pick up sediment deposited during prior runoff events (USDA/EPA, 1976).

In conclusion, the Agency's perception is that it is not possible to predict the extent of overland transport of endrin by erosive processes because of the variable nature of these processes and thus, the efficacy of a barrier strip in reducing endrin runoff cannot be predicted. The Agency concludes that Velsicol's contention that a "worst case" of endrin transport across a ¼ mile barrier strip is 1% of that leaving the treated field is not justified.

(e) *Effect of Vegetation in Attenuating Runoff.* Velsicol concluded that vegetative cover on the proposed barrier strip would further reduce endrin transport by a factor of ten. An exploratory survey (Moubry et el., 1967) of endrin runoff through heavy turf in a Wisconsin orchard was cited, in which no endrin was detectable in runoff water; the water was observed to be devoid of silt. The relevance of this study to cotton runoff is questionable, since it does not appear that cotton fields generally are surrounded by heavy turf. The observations of Willis et el. (1976), quoted above, suggest that very little vegetative cover may be available throughout much of the year in cotton culture. For the cover and management factor appearing in the Universal Soil Loss Equation, a value of 0.34–0.4, corresponding to about 60% reduction in sediment yield, is an approximate value for cotton (USDA/EPA, 1975). This indicates that a factor of ten is too large to be a reasonable estimate of the effect of vegetative cover on a barrier strip in reducing endrin runoff from cotton fields.

(f) *Calculation of Maximum Endrin Concentration.* Based on its estimates of endrin runoff from a treated plot, across a barrier strip, and through vegetation, Velsicol calculated that the maximum concentration in a two acre-foot pond located ¼ mile away from a single treated acre would be 2 ppt. As discussed above, the Agency does not accept these three estimated runoff percentages, or, therefore, the calculated pond concentration based on them. Moreover, the use of a single acre as a plot size is particularly unreasonable; clearly, many acres of cotton could be treated in a single watershed. As noted by Leonard el al. (1976):

> The pesticide load in runoff and on sediment times the areal extent of usage is the pesticide dosage entering the receiving water.

The Agency believes that integrated sampling of a watershed area, in which all of the runoff is channeled through a flume and sampled continuously, is the only reliable way to quantitate pesticide losses in runoff. The studies by Willis et al. (1976) and Smith et al. (1978) are examples of such studies. In the absence of adequate data of this nature, the Agency can not reasonably conclude that Velsicol's calculation of maximum endrin concentration in receiving waters is supported.

(g) *The Arkansas Distance Restriction.* Velsicol stated that a reduction in fish kills in Arkansas following imposition of a ¼ mile aerial application distance restriction from commercial fish ponds and hatcheries demonstrates the efficacy of such restrictions in diminishing runoff transport. Arkansas and Mississippi are areas of intensive commercial catfish farming. Crockett et al. (1975) sampled catfish from 50 farms in 1970 and reported that 76% of the fish samples contained endrin. They concluded that aerial transport of endrin from nearby cotton areas was the most probable route of contamination. They also observed that commercial fish ponds are generally constructed to prevent the entry of surface runoff. Thus it appears likely that the reason that the imposed distance restriction resulted in a decrease in fish kills, to the extent that those data are accurate and complete, was because drift was the main source of contamination of the commercial fish ponds. The Agency accordingly concludes that the alleged success of the distance restriction in Arkansas does not answer the question of reduction in runoff transport.

(h) *The Emergency Exemption in Mississippi.* Velsicol claimed that the imposition of a ¼ mile distance restriction for an emergency exemption involving certain synthetic pyrethroids in Mississippi and the resulting lack of fish kills demonstrates the efficacy of the restriction in diminishing runoff. However, a ¼ mile restriction was imposed as a condition of the emergency exemption use as a precautionary measure to reduce aquatic contamination while adequate data were being developed for registration purposes; it was not imposed on the basis of any particular data or information regarding environmental transport or the effectiveness of a barrier strip in reducing transport. The alleged absence of reported fish kills alone is insufficient to support Velsicol's conclusion. Velsicol did not establish that conditions which cause runoff were associated with the use of the pyrethroids. To the extent that runoff conditions may have been present, the absence of reported fish kills is not evidence that substantial transport did not take place since the transported materials may not have been at lethal concentrations; sublethal concentrations of endrin are of substantial concern to the Agency. Without an adequate analysis and additional empirical data, Velsicol's observation on synthetic pyrethroids gives little, if any, support to its position on the effectiveness of a barrier strip in reducing the transport of endrin by runoff.

(i) *Alabama monitoring data.* The Alabama monitoring data (Elliott, undated) reported a wide range of endrin residues in pond water, sediment, fish, soil, forage, rats and birds. Endrin treatment history was not reported, so that correlation between endrin use and resulting environmental residues is not possible. This study was not designed to evaluate the efficacy of the distance restriction in diminishing endrin residues in water, and no conclusions regarding the efficacy can be drawn from the study.

(j) *Distance Restrictions in Forest Areas.* The United States Forest Service employs distance restrictions for pesticide applications in forest areas primarily to reduce drift. Since vegetative cover and soil surface conditions in forest areas are entirely different from those expected adjacent to southeastern cotton fields, the Agency concludes that distance restrictions used in the forest have no relevance to cotton agriculture.

(k) *Summary.* Velsicol stated that there is overwhelming evidence that a ¼ mile distance restriction would render innocuous any endrin runoff from southeastern cotton fields. The Agency has reviewed all the information submitted by Velsicol concerning this issue, as well as additional information cited above. The Agency concludes that endrin transport to water by runoff would still be a substantial possibility if

the distance restriction were to be imposed, and that no reliable information is available to insure that the attenuation of this transport by a barrier strip would consistently be of the order of magnitude suggested by Velsicol. Accordingly, the conclusions submitted by Velsicol on the issue of runoff cannot be considered adequate to support its proposal of allowing endrin use on cotton in the southeast subject to a ¼ mile distance restriction from water.

Additionally, Velsicol has stated that its proposes distance restrictions from bodies of water "would reduce runoff to innocuous levels even under worst-case circumstances"; that "the Agency has acknowledged the validity of this point with respect to small grains regions and western cotton regions where heavy rainfall is infrequent . . ."; and the "The Agency also agrees with Velsicol that a similar distance restriction of 50 feet is appropriate for the apple orchard use" (Velsicol, p. 24). These statements distort the Agency's position on the effectiveness of barrier strips in reducing runoff. In all cases where the Agency has propose was to reduce to acceptable levels relative to the perceived benefits of usage. In the case of orchards, at the very place cited by Velsicol (PD ⅔, p.157), the Agency stated that:

> Major risks to fish and wildlife would remain because of the high application rate to the terrestrial habitat and because the potential for runoff would be little affected by a distance restriction of 50 feet.

(b) *Small Grains.* In response to the Agency's proposal to permit applications of endrin adjacent to ponds owned by the user, Velsicol has repreated its proposal to prohibit applications within ¼ mile of *all* lakes, ponds, and streams (Velsicol, p. 90). In PD ⅔ the Agency presented its rationale for excepting ponds owned by the user: As a matter of policy, the farmer should have the right to choose between risking his fish and protecting his wheat (PD ⅔, p. 145). Velsicol has given no reason for denying the farmers that option, and Agency sees no reason to change its position.

Dr. Leroy Brooks (1978) has recommended that the distance restriction be reduced to ⅛ mile if endrin is applied by ground equipment. Dr. Brooks' recommendation is consistent with the intent of the use restriction. Drift from a boom ground sprayer two feet above the wheat will travel less than half the distance than will the drift from an airplane at an elevation of 10 feet if both have similar nozzles and pressures. Therefore a ⅛ mile distance restriction is appropriate for such ground equipment and will be so indicated on the label.

4. *Distance Restriction from Human Habitation.* The SAP questioned the basis for the Agency's proposal to prohibit application of endrin within 150 yards of human habitation (SAP, Dec. 15, 1978 pp. 5–6) and recommended that the distance be extended to ¼ mile from human habitation (Fowler, 1978). Velsicol supported the imposition of a quarter-mile restriction. The basis for the Agency's proposal, set forth in PD ⅔ (p. 128), was that the MOS for teratogenic risk estimated for a distance of 150 yards is ample (5500). Neither the SAP nor Velsicol demonstrated any deficiency in the Agency's assessment.

The Agency believes that since there is an ample MOS at 150 yards, the imposition of a ¼ mile restriction would unnecessarily reduce the economic benefits to users. However, the Agency recognizes that its risk estimate assumed compliance by the applicator regarding equipment, wind speed and other restrictions and that in the absence of full compliance, the MOS would vary by an unknown amount. Therefore, in consideration of the recommendations of both the SAP and Velsicol and for consistency in the specification of distances on labels, the Agency will compromise its position and direct that this restriction be modified to read "⅛ mile" (220 yards) instead of "150 yards."

5. *Posting of Contaminated Ponds.* In the event of a fish kill, the Agency proposed that the pond be posted "Contaminated: No Fishing" for a period of one year. Velsicol characterizes this warning as "inadequate" and indicates that a more appropriate warning would be as follows: "Contaminated: Use of this Water for Drinking, Fishing, Swimming or Other Recreational Purposes Is Prohibited" (Velsicol, p. 90). Velsicol's position, however, is unsupported by any analysis. A direct overspray was estimated to produce a concentration of 0.009 mg/l (9 ppb) in a pond 2 feet deep (Velsicol, Exh. 5). Were a woman to drink as much as a gallon of water containing 10 ppb endrin, the MOS would be 2,000. In consideration of the low solubility of endrin in water and its high adsorption on fine particulate matter, the Agency believes that negligible amounts of endrin would be adsorbed by a swimmer. Consequently, consumption of fish caught from contaminated ponds appears to be the only exposure route of significant concern. This concern is adequately dealt with by the Agency's proposal.

Other issues concerning posting have also been raised. One is whether the duration of posting should be less than a year. Another is whether posting is necessary in situations where contamination is likely but the level is below that which kills fish. The latter issue was raised at the SAP meeting (SAP, October 26, 1978, p. 121) but was left unresolved. Unfortunately, available field data are inadequate for precise standard setting. It seems reasonable and prudent, however, to require that, if treatment is made at distances closer than ¼ mile by air or ⅛ mile by ground from ponds owned by the user, that such ponds be posted for a period of 6 months if no fish are killed and 12 months if a fish kill occurs. In any case, fishing may be permitted if laboratory analysis indicates that endrin concentration in the edible portion of fish do not equal or exceed 0.3 ppm (which is the current FDA Action Level for endrin residues in fish), since the MOS for a pregnant woman consuming 315 g (11 oz.) of fish contaminated at this level is 1,000. These restrictions may be revised when a body of data regarding residue reduction in the field becomes available.

6. *Teratogenicity Warning.* The Preliminary Determination proposed that appropriate endrin labels bear a "Warning to Female Workers" that "Excessive Exposure to Endrin May Cause Birth Defects". Velsicol opposes the inclusion of such a warning on endrin labels. (Velsicol, p. 88.) The bases for Velsicol's opposition and the Agency's responses are:

a. *The margin of safety for applicators is 300 and this is three times the acceptable level.* Barring accidents and assuming that they follow label instructions, applicators and other workers are at little risk from the teratogenic effects of endrin. One of the purposes of the warning, however, is to insure that vulnerable female workers are aware of the potential risks so that they may exercise the appropriate precautions and respond properly to accidental exposure. One drop of a 19.7% EC formulation contains 10 mg of endrin and 10% absorption of that drop provides an MOS of only 75 for teratogenic effects. Certainly such potential exposure should be of substantial concern. Further, as discussed above, the Agency does not conclude that an MOS of 100 is "acceptable" for all teratogenic risks.

b. *Also, the phrase "excessive exposure to endrin may cause birth defects" is factually inaccurate because exposure to threshold teratogenic levels of endrin would cause acute toxicity or death to humans before such exposure*

could cause birth defects (see p. 41 of this response and Exhibit 43). The references cited do not elaborate on the above issue but only indicate that endrin may cause single convulsions in humans at dosages of 0.20 to 0.25 mg/kg and multiple convulsions of 1 mg/kg. It is the Agency's position that, since teratogenic effects in the hamster were observed at doses which did not produce convulsions or other overt signs of toxicity, the same relative relationship may exist for humans. That is, a teratogenic hazard in humans may occur before any toxic warning signs are observed. Velsicol's argument would have some validity only if terata in test animals were associated only with severe toxic effects in the dams, which is not the case with endrin. In addition, even if endrin did cause acute toxicity in humans at doses below the teratogenic threshold, the teratogenic concern would not thereby be eliminated.

The Agency recognizes, however, that the Warning to Female Workers "Excessive exposure to endrin may cause birth defects" can be modified to affirmatively and explicitly reflect the Agency's scientific conclusions concerning the teratogenicity of endrin, while at the same time adequately warning vulnerable female workers so that they may exercise appropriate precautions. On the first point, one commenter (Brooks, 1978) has suggested that the warning indicate that the evidence concerning birth defects relates to experimental animals; on the second, Velsicol has asserted that only pregnant workers are at risk of birth defects (although Agency notes that the period of vulnerability has not been established). Accordingly, the Agency has determined to change the first sentence of the Warning to Female Workers from "Excessive exposure to endrin may cause birth defects" to the following two sentences, "The United States Environmental Protection Agency has determined that endrin causes birth defects in laboratory animals. Exposure to endrin during pregnancy should be avoided."

c. *If a teratogenicity warning is warranted for a weak teratogen such as endrin with only a remote likelihood of exposure to pregnant women, strong teratogens to which women are commonly exposed * * * should contain teratogenicity warnings as well.* The Agency does not agree that endrin should be characterized as a "weak" teratogen.[7] It agrees, in principle, that many compounds should bear teratogenicity warnings and intends to implement that principle when appropriate.

7. *Protective Clothing for Workers.* The USDA commented, "We question the advisability of requiring protective clothing for all female workers. The teratogenicity risk, as defined, should apply only to female workers capable of bearing children." On the other hand, Velsicol states, "Protective clothing should be worn by men as well as women. This is because any hazards to applicators or field workers would be from acute exposure, not from a teratogenic hazard" (Velsicol, p. 91).

Since the risk criterion for acute dermal toxicity for endrin had been rebutted by Velsicol, the Agency determined only to impose additional protective clothing requirements for female workers since they were imposed on the basis of a teratogenic risk. On that point, although it is true that only women who are capable of bearing children are at risk, the Agency believes that it is prudent to impose protective clothing requirements for all women involved in application of endrin since the vast majority of such female workers are likely to be of childbearing age.

8. *Warnings on Prophylactic Use.* In its Notice of Determination, the Agency proposed the following language, *"Prophylactic Use.* Unnecessary use of this product can lead to resistance in pest populations and subsequent lack of efficacy." The Agency received several comments on this proposal.

The USDA commented, "We do not believe the statement on prophylactic use adds anything to the usefulness of the label information and should be deleted" (Bergland, 1978). The SAP report indicated that, "The Panel is concerned with the risks inherent with the prophylactic use of endrin and urges that the Agency reexamine the label statements regarding such use" (Fowler, 1978). Velsicol's comment was, "Velsicol proposed to prohibit prophylactic use of endrin. The Agency's proposed label language, however, merely is in the form of a warning and is not emphatic enough deterrent against prophylactic use" (Velsicol, p. 90). Finally, Dr. Ross Byers (Byers, 1978) wrote:

> The statement, page 33 concerning "Prophylactic Use" is not based on fact. Resistance in vole populations is not the result of using Endrin when not needed! Where resistance develops is when partial control is achieved through low dosage applications and/or poor application technique. Partial control allows sufficient animals within the area to continue the reproduction of survivors in the presence of the toxicant. Pine vole populations were first found resistant to Endrin in the areas most seriously infested and where growers were using reduced rates per acre and/or using rather poor application techniques.

The comments of USDA and the SAP on prophylactic use are diametrically opposed and in neither case is the basis for the position fully articulated. The Agency can only respond by a fuller explanation of its position.

The Agency considered imposing a prohibition against prophylactic use (that is, use when economic infestations are not present), such as that encouraged by Velsicol, rather than a warning. The Agency decided against the prohibition because it believed such a restriction would be generally unenforceable. Unless substantial damage is visible, it is usually not possible to determine, after control measures have been applied, whether or not the controlled populations had been at economic levels. In any event, the Agency believes that the educational aspect of the proposed label language accomplishes the Agency's primary objective in this respect, so that a prohibition *per se* is not necessary.

Dr. Byers' account is not necessarily at variance with the principles on which the Agency relies in its concerns about resistance. Dr. Byers indicates that repeated usage was necessary because of poor control and implicates the poor control as a critical factor in the development of resistance. While, historically, this may have been the case in Virginia, the reason for making frequent applications is not relevant to the principles of natural selection that lead to genetic resistance; selection should be even more rapid if repetitive control is highly effective. Dr. Byers' comment does highlight the importance of proper application methods and the proposed label changes regarding rates and equipment should help to prevent situations such as those described by Dr. Byers.

[7] Velsicol's characterization of endrin as a "weak" teratogen apparently derives from statements made by one of its consultants regarding the Chernoff study (Velsicol, Exh. 30, p. 8 and SAP, October 26, 1978, p. 51 and Velsicol, Exh. 32). At the SAP meeting, Velsicol's consultant stated, "* * * there is some teratogenic potential, albeit a low level for this compound [endrin], but that potential occur only at maternal toxic levels or very near to maternal toxic levels" (SAP, p. 51). The basis for this position has never been made clear. Previously, the consultant stated, "A single dose as high as 10 mg/kg produced no maternal toxicity and had no effect on intrauterine mortality or growth of the offspring. Two types of malformations * * * were significantly increased at the three highest single doses, 5.0, 7.5, and 10.0 mg/kg" (Velsicol, Exh. 30, pp. 5–6). It appeared, on further discussion at the SAP meeting (SAP pp. 51–4), that the consultant's misperceptions of the data should have been rectified. The record is clear that frank terata were produced by single doses of endrin that were substantially below doses which caused observable maternal toxicity to hamsters.

9. *Enforcement.* The EDF notes that pests other than those for which the Agency proposes to maintain registration may occur in small grains and orchards and asks, "How does the 1978 amendment (Section 2(ee)), which allows use on a site against pests not named on the label, affect these 'cancelled' uses?" (Hinkle, 1979). The Agency was cognizant of this problem and addressed it in accordance with Section 2(ee) of FIFRA by requiring that the labeling specifically state that endrin may be used "only" for the pests specified on the label, after it was determined that the use of endrin against other pests would cause an unreasonable adverse effect on the environment. The Agency is aware that strict enforcement of label restrictions may be impossible but believes that, where its regulatory actions have been reasonable, an adequate level of compliance can be anticipated. Any substantial evidence that misuse has become a common practice would provide a basis for further regulatory action.

10. *Grasshopper Control.* EDF strenously opposes the "proposed use of endrin" to control grasshoppers, citing the existence of risks to wildlife and livestock from the use of endrin on wheat and the availability of safer alternatives (Hinkle, 1979). To clarify the status of this use, when the Agency began its risk/benefit analysis, the only registration for endrin to control grasshoppers was for small grains in Montana. This old state registration is now pending as an application for federal registration for use in Montana under 40 CFR Section 162.17. While PD 2/3 was in preparation, the Agency also received endrin registrations for special local needs in the states of Nebraska and Oklahoma, pursuant to Section 24(c) of FIFRA, to control grasshoppers both in winter wheat and as perimeter treatments in noncropland (but not on rangeland). However, the 24(c) registrations for use in Oklahoma expired on December 31, 1978 and the Agency is not aware of any proposal for renewal. The registrations for Nebraska will expire on August 2, 1979, prior to the time endrin would be used on winter wheat for grasshopper control. Further, at the time Nebraska registered these uses, it indicated that they would not be renewed unless Velsicol supplied additional data supporting the safety and efficacy of the use. In the event that Oklahoma or Nebraska should renew these registrations under Section 24(c), the Agency shall then determine whether or not to disapprove them.

Thus the only decision pending at this time concerning the use of endrin to control grasshoppers is on small grains only (not non-cropland and not rangeland) in Montana only. EDF's submission does not appreciable contribute to the Agency's analysis of this use, since much of the risk data referred to by EDF was not submitted for review by the Agency, and it does not appear from EDF's description that it was specifically related to endrin's use for grasshopper control. In light of data submitted by Velsicol concerning the efficacy of endrin for controlling grasshoppers (Coppock and Pitts, Undated), the Agency has no basis to amend its regulatory decision set forth in PD 2/3 concerning the use of endrin to control grasshoppers on small grains in the State of Montana only.

11. *Conifer Seed Treatment.*[8] PD 2/3 concluded that the terms and conditions of registration for endrin products used for treatment of conifer seed should be modified to include an "Application Restriction" stating "Do not apply when large numbers of migratory birds are expected." Althought the agency did not receive any formal comments on the language of this modification, the Agency has determined upon its own re-examination that some ambiguity will be removed, and the intent of the restriction clarified, by amending the "Application Restriction" statement to read: "Do not sow treated seed when large numbers of migratory birds are expected."

D. *Comments Relating to Procedural Matters.* The Agency has received several comments with regard to the RPAR process and how, in the case of endrin, the Agency has administered the process. Since some of these comments reflect misunderstanding, misconstrue the record, or otherwise influence the public perception of Agency activities, the issues raised by these comments require some discussion and clarification.

1. *Availability of the Agency's Rebuttal Analysis.* Velsicol has stated that "the [RPAR] regulations require the Administrator to issue *prior* to initiation of a risk/benefit analysis a notice of determination as to whether the cited risk presumptions have been rebutted. *See* 40 CFR 162.11(a)(5). In the case of the endrin RPAR, however, the Agency's rebuttal analysis was not made available to Velsicol until *after* the Agency's risk/benefit analysis had been completed." (Velsicol, pp. 5–6, FN1, emphasis in original).

Velsicol has misinterpreted the relevant provisions of the RPAR regulations. It is true that § 162.11 (a)(5)(ii) states that * * * if after review of the evidence submitted in rebuttal the Administrator determines that the applicant or registrant has not rebutted the presumption * * *, then he shall issue a notice in accordance with sections 3(c)(6), or 6(b)(1) of the Act * * *, as appropriate, for the use(s) of the pesticide subject to the presumption and not rebutted." However, § 162.11 (a)(5)(iii) specifically provides that "in determining whether to issue a notice pursuant to section 3 (c)(6) or section 6 (b)(1) * * * in accordance with paragraph (a)(5)(ii) of this § 162.11, the Administrator may, in his discretion, take into account staff recommendations resulting from preliminary analysis, if any, concerning the balancing of risks against benefits." In other words, the regulations clearly contemplate that the Administrator may evaluate benefits, and the balancing of those benefits against risks, in determining whether or not to issue a notice of intent to cancel or deny registration in cases where the risk presumptions have not been rebutted. Contrary to Velsicol's assertions, nothing in those regulations or otherwise requires the Administrator to issue a separate document as to whether the risk presumptions have been rebutted, prior to initiating the risk/benefit analysis.[9]

2. *Use of Relevant Information on Risk Assessment.* Velsicol has alleged that the Agency "apparently was unable to take into account * * * in Position Document 2/3 significant risk information on teratogenicity and other matters which had been developed at the Agency's request" (Velsicol, pp. 7 and 17). Although the Agency extended the opportunity to Velsicol to comment upon the teratogenicity issue prior to the issuance of PD 2/3, the matters referred to were certainly not developed "at the Agency's request." Moreover, while the Agency indicated a willingness to consider any new information for its

[8] Endrin is also used for watermelon seed treatment (Florida) and melons and vegetable seed treatment (California). The Agency proposed to accept these uses without *any* restrictions. No comments were received on this proposal.

[9] Velsicol also argues that the Agency's alleged refusal to disclose its rebuttal analysis prior to completion of its risk/benefit analysis "unnecessarily delayed Velsicol from developing further information on the Agency's remaining risk concerns." (*Ibid*). Even assuming that the regulations contemplate repeated opportunities for registrants to rebut presumptions of risk (by "developing further information" after it is determined that the presumption was not rebutted by the initial submission), the Agency does not believe that Velsicol was prejudiced in the circumstances of this case. In any event, the Agency accepted Velsicol's comments on PD 2/3 on January 5, 1979—over two months after Velsicol received a copy of PD 2/3.

potential impact on the pending decision, preliminary reviews by the Agency indicated that none of Velsicol's last minute submissions contained any information that required any change in the Agency's position. And, as indicated in this PD 4, the Agency has reviewed and commented on all relevant information supplied by Velsicol before making this final decision, so that the Agency's review process has not resulted in any prejudice to Velsicol.

3. *Development of State Programs for Use on Cotton.* Representatives of the states of Alabama, Arkansas and Mississippi requested the Agency to defer the final decision on the use of endrin on cotton until the States can develop programs that would substantially alter the risk/benefit picture (Lane, 1979; Lincoln, 1979a; Coley, 1979). The Agency responded by indicating that it wishes to encourage the development of such programs in general but, in the absence of new information, the Agency had no basis for deferring a decision already overdue (Johnson, 1979a). It also indicated that should new information on risk/benefit relationships be developed, including the institution of state programs which would establish appropriate controls to enhance the risk/benefit ratio for the use of endrin on cotton, it would then be appropriate for the Agency to reconsider the registration of endrin for use on cotton in areas east of I–35.

The state of Arkansas then proposed that the State would establish a new category for certain restricted use pesticides such as endrin, in effect making them available for use only under emergency conditions to be identified by extension personnel (Martin, 1979). The Agency responded that many specific details of such a program would have to be developed for further consideration, that a revised risk/benefit analysis would be necessary, and that any new decisions proposed by the Agency would require reconsultation with the FWS and public review (Johnson, 1979b). Thus, the Agency still has no basis for deferring its decision but will reconsider it whenever it is justified by the availability of new information.

III. Conclusions

After considering the comments received from the USDA, the SAP, the FWS, Velsicol and other concerned parties, the Agency has decided to make the following revisions to the Notice of Determination:

A. *Registration for Use on Cotton.* 1. *Warning to Female Workers.* "Excessive exposure to endrin may cause birth defects" will be amended to read, "The United States Environmental Protection Agency has determined that endrin causes birth defects in laboratory animals. Exposure to endrin during pregnancy should be avoided."

2. *Aerial Application.* "Do not release this material at greater than 19 feet height above the crop" will be amended to read" "* * * 10 feet height above the crop."

3. *Application Restrictions.* "Do not use this product within 150 yards of human habitation" "will be amended to read "Do not apply this product within ⅛ mile of human habitation."

"Do not use this product within ¼ mile of streams, lakes, or ponds. Application may be made within ¼ mile of ponds owned by the user, but application within 200 yards of such ponds may result in fish kill" will be amended to read, "Do not apply this product by air within ¼ mile or by ground within ⅛ mile of lakes, ponds, or streams. Application may be made at distances closer to ponds owned by the user but such application may result in excessive contamination and fish kills."

4. *"Procedures to be Followed if Fish Kills Occur.* In case of fish kills, fish must be collected promptly and disposed of by burial. At ponds, post signs stating: Contaminated: No Fishing. Signs must remain for one year after fish kill has occurred" will be amended to read, *"Procedures to be Followed if Fish Kills Occur or if Ponds are Contaminated.* In case of fish kills, fish must be collected promptly and disposed of by burial. Ponds in which fish kills have occurred, and user-owned ponds exposed to endrin by application at distances closer than otherwise prohibited, must be posted with signs stating: 'Contaminated: No Fishing.' Signs must remain for one year after a fish kill has occurred or for six months after lesser contamination unless laboratory analysis shows endrin residues in the edible portion of fish to be less than 0.3 parts per million (ppm)."

5. Add: "For use in areas west of Interstate Highway #35 only".

B. *Registration for Use on Small Grains.* Amendments 1, 2, 3, and 4 for cotton (A, above) are applicable for small grains.

C. *Registration for Use in Apple Orchards.* 1. Amend the "Warning to Female Workers" as above.

2. *Pests for Which this Product May be Applied,* "This product may be applied to control the following pests only: Pine vole; western meadow vole" will be amended to read, "This product may be applied to control the following pests only: Eastern United States-Pine Voles (*Microtus pinetorum);* Western United States-Meadow Voles (*Microtus species*)".

3. *Equipment.* Add, "Apply by ground equipment only."

4. *Procedures to be Followed If Fish Kills Occur.* "In case of fish kills, fish must be collected promptly and disposed of by burial. At ponds, post signs stating: 'Contaminated: No Fishing'. Signs must remain for one year after fish kill has occurred." will be amended to read "In case of fish kills, fish must be collected promptly and disposed of by burial. Ponds in which fish kills have occurred must be posted with signs stating: 'Contaminated: No Fishing'. Signs must remain for one year after a fish kill has occurred unless laboratory analysis shows endrin residues in the edible portion of fish to be less than 0.3 parts per million (ppm)."

D. *Registrations for Use on Sugarcane.* Amend the "Warning to Female Workers" as above.

E. *Registration for Treatment of Conifer Seed Application Restrictions.* "Do not apply when large numbers of migratory birds are expected" will be amended to read: "Do not sow treated seed when large numbers of migratory birds are expected."

F. *Registrations for Use as Tree Paint.* Amend the "Warning to Female Workers" as above.

G. *Registration of Use on Alfalfa and Clover Seed Crops.* Amendments 1, 2, 3, and 4 for cotton (A, above) are applicable to alfalfa and clover seed crops.

H. *Registration for Use in Enclosed Bird Perch Treatments.* Amend the "Warning to Female Workers" as above.

Except for the above amendments, all provisions of the Notice of Determination will be adopted as the final decision on the registration and continued registration of pesticide products containing endrin.

Bibliography

Akesson, Norman B. 1977. The Technical Advisory Committee on Label Restrictions for Endrin-Methyl Parathion 1.6 EC and Endrin 1.6 EC. Report from the committee's meeting in Denver, Colorado, December 8–9, 1977.

Akesson, Norman B. 1978. Letter from Agricultural Engineering Department, University of California, Davis, California to Lawrence Ebner, Sellers, Conner and Cuneo, Attorneys and Counselors, Washington, D.C., defining water bodies and streams for endrin use and limitations. August 25, 1978.

Alley, E. G., B. R. Layton, and J. P. Minyard, Jr. 1974. Photoreduction of Mirex in aliphatic amines. J. Ag. Food Chem. *22* (4), 727–9.

Anderson, Elizabeth L. 1978a. Memo from Executive Director, CAG, EPA, to H. Wade Fowler, Executive Secretary, FIFRA Science Advisory Panel (SAP), transmitting a response to Melvin Reuber's critique of the endrin carcinogencity review. December 7, 1978.

Anderson, Elizabeth L. 1978b. Memo from Executive Director, CAG, EPA, to H. Wade Fowler, Executive Secretary, FIFRA SAP, transmitting additional comments to Melvin Reuber's critique of CAG'S endrin review. December 13, 1978.

Baker, R. D., and H. G. Applegate. 1974. Effect of ultraviolet radiation on the persistence of pesticides. Texas J. Sci. *25* (1–4), 53–9.

Bergland, Bob. 1978. Letter from Secretary, U.S. Department of Agriculture, to Douglas Costle, Administrator, U.S. Environmental Protection Agency, responding to EPA's notice of determinations concluding the endrin RPAR. November 22, 1978.

Blalock, T. C. 1978. Letter from Associate Dean, North Carolina State University School of Agriculture and Life Sciences, to Technical Services Division, OPP, EPA, commenting on proposed actions on endrin. November 14, 1978.

Brooks, Leroy. 1978. Letter from Extension Specialist, Kansas Cooperative Extension Service, to Dr. Paul W. Bergman, USDA, concerning endrin use on small grains and endrin use restrictions. November 20, 1978.

Bushong, Clayton. 1978. Memo to Kyle Barbehenn, Project Manager, SPRD, OPP, EPA, concerning "Opinions on Endrin" Letter with Four Separate Risk Analyses Attached. June 28, 1978.

Byers, Ross E. 1978. Letter from Associate Professor of Horticulture, Virginia Polytechnic Institute and State University, to Dr. James P. Barnett, Endrin Impact Assessment Team Leader, USDA, concerning endrin for vole control. November 14, 1978.

Castro, T. F., and T. Yoshida. 1971. Degradation of organochlorine insecticides in flooded soils in the Philippines. J. Ag. Food. Chem. *19* (6), 1168–70.

Chernoff, Neil, Robert J. Kavlock, and L. Earl Gray, Jr. 1978a. Endrin-induced perinatal toxicity studies in the hamster with a review of the pertinent literature. Health Effects Research Laboratory, Experimental Biology Division, EPA. Research Triangle Park, North Carolina (Unpublished) August 25, 1978.

Chernoff, Neil, Robert J. Kavlock and L. Earl Gray, Jr. 1978b. Memo to Kyle Barbehenn, SPRD, OPP, EPA, concerning review of statements by Drs. A. J. Steffek and J. G. Wilson about endrin teratology studies. November 13, 1978.

Coley, Jack. 1979. Letter from Mississippi State Entomologist, to Douglas Costle, Administrator, EPA, concerning possible State restrictions to allow some uses of endrin. January 24, 1979.

Coppage, David. 1978. Memo from Aquatic Biologist, EEB, HED, OPP, EPA, to Kyle Barbehenn, Project Manager, SPRD, OPP, EPA, concerning theoretical movement of endrin from soil into water and the effect of this movement on non-target organisms. December 13, 1978.

Coppock, Stanley. 1976. Letter from Extension Entomologist, Cooperative Extension Service, Oklahoma State University, Stillwater, Oklahoma, to Edwin L. Johnson, OPP, EPA. December 29, 1976.

Coppock, Stanley, and Terry Pitts. Undated. Grasshoppers and insecticides for their control. Oklahoma State University Extension Service. (Unpublished.)

Crockett, A. B., G. B. Wiersma, H. Tai, and W. Mitchell. 1975. Pesticide and mercury residues in commercially grown catfish. Pest. Monit. J. *8* (4), 235–40.

EPA. 1977. Preliminary Benefit Analysis of Endrin. Economic Analysis Branch, (EAB), CED, OPP, Washington, D.C.

EPA. 1978. Endrin Position Document 2/3. SPRD, OPP, USEPA, October 20, 1978.

Fowler, H. Wade, Jr. 1978. Memorandum from Executive Secretary, FIFRA SAP, to Edwin Johnson, Deputy Assistant Administrator, OPP, EPA, transmitting the SAP's findings on endrin. December 21, 1978.

Greenwalt, Lynn, A. 1978a. Director, Fish and Wildlife Service, U.S. Department of the Interior, to Douglas Costle, Administrator, EPA, concerning effects of endrin on populations of endangered species. June 8, 1978.

Greenwalt, Lynn, A. 1978b. Letter from Director, Fish and Wildlife Service, U.S. Department of the Interior, to Douglas M. Costle, Administrator, EPA, amending biological opinion of June 8, 1978. December 14, 1978.

Greenwalt, Lynn, A. 1979. Letter from Director, Fish and Wildlife Service, U.S. Department of the Interior, to Douglas M. Costle, Administrator, EPA, revising biological opinion of December 14, 1978. March 1, 1979.

Hinkle, Maureen. 1979. Letter from Pesticides Monitor, Environmental Defense Fund, to U.S. Environmental Protection Agency, concerning the preliminary determination of the endrin RPAR. February 15, 1979.

Johnson, Edwin L. 1979a. Letter from Deputy Assistant Administrator, OPP, EPA, to McMillan Lane, Commissioner, Alabama State Department of Agriculture and Industries, concerning state programs to affect endrin risk/benefit balancing. March 6, 1979.

Johnson, Edwin L. 1979b. Letter from Deputy Assistant Administrator, OPP, EPA, to Mr. Wallace Martin, Arkansas State Plant Board, concerning a proposed state program for special restricted-use pesticides. April 16, 1979.

Lane, McMillan. 1979. Letter from Commissioner, Alabama State Department of Agriculture and Industries, to Douglas Costle, Administrator, EPA, concerning the need for endrin for use on Alabama cotton. January 23, 1979.

Lincoln, Charles. 1978. Letter from member, Arkansas State Plant Board, to Edwin L. Johnson, Deputy Assistant Administrator, OPP, EPA, concerning presumptions supposedly rebutted at the SAP meeting. March 15, 1979.

Lincoln, Charles. 1979. Letter from member, Arkansas State Plant Board, to Douglas Costle, Administrator, EPA, concerning possible state restrictions to preserve some endrin uses. January 19, 1979.

Leonard, R. A., G. W. Bailey, and R. R. Swank, Jr. 1976. Transport, detoxification, fate, and effects of pesticides in soil and water environments, in Land Applications of Waste Materials, published by Soil Conservation Society of America, Ankeny, Iowa.

Martin, Wallace. 1979. Memo from Chairman, Arkansas State Plant Board, to EPA, concerning state restriction of pesticide uses. March 14, 1979.

Matsumura, F., V. G. Khanzilkar, K. C. Patil, and G. M. Boush. 1971. Metabolism of endrin by certain soil microorganisms. J. Agric. Food Chem. 19:27–31.

Moubry, R. J., J. M. Helm, and G. R. Myrdal. 1968. Chlorinated pesticide residues in an aquatic environment located adjacent to a commercial orchard. Pest. Monit. J. *1* (4), 27–9.

Mount, D. I. and G. J. Putnicki. 1966. Summary report of 1963 Mississippi fish kill. In: Trans. 31st N. Amer. Wildlife Conf. 177–184. Wildl. Manag. Inst., Washington, D.C.

Pionke, H. B., and G. Chesters. 1973. Pesticide-sediment-water interactions. J. Environ. Qual. *2* (1), 29–45.

Reuber, Melvin D. 1978a. Critique of the carcinogenicity studies on endrin in animals. November 2, 1978.

Reuber, Melvin D. 1978b. Carcinogenicity of endrin. Frederick Cancer Research Center, Frederick, M.D. (Unpublished) November 28, 1978.

Science Advisory Panel. 1978a. Transcript of Proceedings of FIFRA SAP Meeting, October 26, 1978, in Arlington, Virginia. Reported by Acme Reporting Company, Washington, D.C.

Science Advisory Panel. 1978b. Transcript of Proceedings of FIFRA SAP Meeting, December 14–15, 1978, in Arlington, Virginia. Reported by Acme Reporting Company, Washington, D.C.

Seabolt, Buford. 1978. Memo to Dr. Ken Macek concerning endrin residues from NPMP (fish). September 18, 1978.

Severn, David J. 1978. Memo from Chemist, EFB, HED, OPP, EPA, to Kyle Barbehenn, Project Manager, SPRD, OPP, EPA, concerning Dr. V. H. Freed's statement to the SAP on endrin runoff. November 9, 1978.

Smith, C. N., R. A. Leonard, G. W. Langdale, and G. W. Bailey. 1978. Transport of agricultural chemicals from small upland piedmont watersheds.

Sparr, B. I., W. G. Appleby, D. M. DeVries, J. V. Osmun, J. M. McBride, and G. L. Foster. 1966. Insecticide residue in waterways from agricultural use, in Organic Pesticides in the Environment, American Chemical Society, Washington, D.C.

Stickel, William H., William L. Reichel; Donald L. Hughes. Undated. Endrin in birds: lethal residues and secondary poisoning. Patuxent Wildlife Research Center, U.S. Fish and Wildlife Service, Laurel, M.D. (Unpublished).

USDA. 1968. Monitoring for chlorinated hydrocarbon insecticide residues in soybeans—1966. Pesticide Monit. J. *2* (1), 58–67.

USDA/EPA. 1975. Control of Water Pollution from Cropland. Vol. I. Report No. ARS–H–5–1.

USDA/EPA. 1976. Control of Water Pollution from Cropland, Vol. II. Report No. ARS–H–5–2.

USDA/State Assessment Team on Endrin. Pesticide Impact Assessment: Endrin. November 4, 1976.

Velsicol Chemical Corporation. 1979. Response of registrant Velsicol Chemical Corporation to the preliminary determination concerning the rebuttable presumption against registration and continued registration of pesticide products containing endrin. 91 pp. + 61 Exhibits. January 5, 1979.

Willis, G. H., L. L. McDowell, J. F. Parr, and C. E. Murphree. 1976. Pesticide concentrations and yields in runoff and sediment from a Mississippi Delta watershed. Proc. Fed. Inter-Agency Sediment. Conf., 3rd.

[FR Doc. 79–22708 Filed 7–24–79; 8:45 am]

BILLING CODE 6560–01–M